# Development of National Drug Policy in the State of Kuwait

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# Development of National Drug Policy in the State of Kuwait

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## ABSTRACT

This Thesis examines the benefits and usefulness of a National Drug Policy (NDP) for the developing of the Health Care System in Kuwait. The NDP is one of the most important structures of the Health System which can lead to improved health services by establishing guidelines, proposals and directives to organize, structure and regulate health legislation; it is of help to ensure the availability of quality, safety and efficacy in using medicines and it can reduce the irrational use of medicines. The NDP is a frame work between the government, schools and universities, media, health professionals, pharmaceutical industries and companies and public. It is cooperation between the public and private sectors to achieve the goal of access to good quality medicines for all. However there are many key factors which need to be examined before the National Drug Policy is introduced and these are considered the baseline for establishing a good policy, and includes; selection of essential drugs, affordability of drugs, drug financing, supply management, drug regulation, rational use of drugs, drugs registration, purchasing of drugs, health research and human resource development. During this research study from 2012 – 2015 several visits to the public and private health areas, were undertaken. At this time there were discussions with 121 health professionals and data was collected and this indicated that in Kuwait there are no such policies. This is despite the availability of financial means, specialized human resources and the existence of the ministerial decisions and regulations governing the health sector in both public and private, whether hospitals, health centers, pharmacies and health departments. In addition it is suggested that the process of a good NDP should be built around 3 main components which includes: 1.Development, 2. Implementation and 3. Monitoring and Evaluation. Therefore the establishing of a NDP without implementation and monitoring is not enough and does not achieve the desired results. The aim of this Thesis is to establish a NDP in the State of Kuwait. This policy is necessary for the State of Kuwait to ensure development an improvement of the Health Care System and ensure better health for population.

## DEDICATIONS

***To my parents***

*For their endless guidance, prayers, and caring love*

***To my Lovely wife***

*Who made all of this possible, for her endless encouragement and patience*

***To my lovely daughter FATIMA***

***and***

*To my dear son* ***YOUSIF***

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## List of Abbreviations

| Abbreviation | Definition |
|---|---|
| **ADR:** | Adverse Drug Reaction |
| **ANOVA:** | Analysis of Variance |
| **ARV:** | Antiretroviral |
| **ASEAN:** | Association of South-East Asian Nations |
| **CAQDAS:** | Computer Assisted Qualitative Data Analysis |
| **CER:** | Cost-Effectiveness Ratios |
| **CG:** | Gliding Containers |
| **CMS:** | Central Medical Stores |
| **CPP:** | Certificate of Pharmaceutical Products |
| **CR:** | Container Rack |
| **CT:** | Computerized Axial Tomography |
| **DRA:** | Drug Regulatory Authority |
| **EDL:** | Essential Drug List |
| **EDXRD:** | Energy Dispersive X-Ray Diffraction |
| **EMEA:** | Europe, Middle East and Africa |
| **EML:** | Essential Medicines List |
| **EPI:** | Expanded Program on Immunization |
| **EU:** | European Union |
| **FDA:** | Food and Drug Administration |
| **FIP:** | Federation of International Pharmacists |
| **GATT:** | General Agreement on Tariffs and Trade |
| **GCC:** | Gulf Cooperation Council |
| **GDP:** | Gross Domestic Product |
| **GLP:** | Good Laboratory Practise |
| **GMP:** | Good Manufacturing Practice |

| | |
|---|---|
| **GNDP:** | Ghanaian National Drug Policy |
| **GPP:** | Good Pharmacy Practice |
| **HIV:** | Human Immunodeficiency Virus |
| **HPLC:** | High Performance Liquid Chromatography |
| **ICDRA:** | International Conference of Drug Regulatory Authorities |
| **IMPACT:** | International Medical Products Anti-Counterfeiting Taskforce |
| **INN:** | International Non-proprietary Names |
| **INRUD:** | International Network for the Rational Use of Drugs |
| **IPRS:** | International Property Rights |
| **JRDL:** | Jordan Rational Drug List |
| **KABP:** | Knowledge, Attitudes, Beliefs and Practice |
| **KD:** | Kuwaiti Dinar |
| **KIA:** | Kuwait Investment Authority |
| **KMOH:** | Kuwaiti Ministry of Health |
| **KSA:** | Kingdom of Saudi Arabia |
| **MCC:** | Medicines Control Council |
| **MHRA:** | Medicines and Healthcare Products Regulatory Agency |
| **MOH:** | Ministry of Health |
| **MRI:** | Magnetic Resonance Imaging |
| **MSH:** | Management Sciences for Health |
| **NDP:** | National Drug Policy |
| **Nedlist:** | Namibia Essential Drugs List |
| **NGOs:** | Non-Governmental Organizations |
| **NHIF:** | National Health Insurance Fund |
| **NPMP:** | National Pharmaceutical Master Plan |
| **NSAIDs:** | Non-Steroidal Anti-Inflammatory Drugs |
| **OAU:** | Organization of Africa Unity |

| | |
|---|---|
| **OTC:** | Over-The-Counter- |
| **PDE5i:** | Phosphodiesterase type 5 inhibitor |
| **PHC:** | Primary Health Care |
| **PHD:** | Philosophiae Doctor |
| **PHRplus:** | Partners for Health Reformplus |
| **PILs:** | Patient Information Leaflets |
| **QA:** | Quality Assurance |
| **SFFC:** | Spurious/Falsely-labelled/ Falsified/Counterfeit |
| **SOPs:** | Standard Operating Procedure |
| **SPCs:** | Summaries of Product Characteristics |
| **SPSS:** | Statistical Package for the Social Sciences |
| **TPA:** | Trade Promotion Authority |
| **TRIPs:** | Trade-Related Intellectual Property Rights |
| **UK:** | United Kingdom |
| **UNICEF:** | United Nations International Children's Emergency Fund |
| **USA:** | United State of America |
| **USD:** | United State Dollar |
| **UV:** | Ultraviolet |
| **WHO:** | World Health Organization |
| **WTO:** | World Trade Organization |

## Chapter 1.0: Introduction

Drugs are biochemicals used to combat the effect of diseases, their prevention and cure or diagnosis or treatment or improvement of physical or mental health. They are also known as ‘medicines’ when used for cure and are taken by mouth or injected to blood directly or applied over to the surface of the body (WHO, 2011).

Drugs play an important role in protecting and maintaining human life and health, for that reason many countries governments, pharmaceutical companies and international organizations, whether they are based in developed or developing countries allocate very large amounts of money to scientific research and studies that contribute to the discovery, development and ensuring quality of medicines which can provide support when encountering and dealing with diseases and epidemics throughout the world.

In addition the Ministries of Health in countries and other agencies try to ensure drug access to the largest number of people in a country, which helps to decrease the mortality and morbidity.

It has been suggested that ‘health and access to essential drugs’ are considered fundamental human rights (WHO, 2003; MSH, 2001). However, access and use of essential drugs worldwide is still far from optimal for a large proportion of the human population (WHO, 2003; MSH, 2001).

It is estimated that 25-50% of the people living in developing countries and a small number from developed countries do not have access to essential medicines. It is proposed that this is influenced by a series of factors such as political, economic and social conditions which can vary between different countries and that there is an inverse correlation between drug development/production and availability to the population. Reasons for this are lack of availability of drugs in certain areas of the world, high prices of essential drugs, absence of sufficient trained professionals and infrastructure to support the delivery of essential drugs to populations in need

wherever appropriate . Moreover additional challenges such as the increase of incidence of chronic disease, caused by the increase in human life-expectancy, the emergence of new serious diseases such as AIDS, the development of drug resistance of previously known and managed life-threatening conditions (such as malaria, tuberculosis), can add more pressure on a health authorities ability to meet the increasing health demands (WHO, 2003; MSH, 2001).

As indicated above the provision of health support is very expensive and covers a very large area. The organization of pharmaceutical services should not only emphasize the availability of drugs, but cover a range of aspects to include services that deal with the quality of medicines, availability of health-care support, which will assist in ensuring the reduction of the spread of disease and sustainable development for health in the long-term.

There also has to be taken into account the very many country-wide and local problems and difficulties facing a health organization and the local communities in supply and organization of medicines, including: availability, affordability, access to the medication, rational use, counterfeiting, storage and distribution, pricing, ensuring quality, safety and efficacy of the drugs and other problems related to the medicines, which in turn lead to difficulty in the face of disease and lead to a reduction in the level of health care system.

For these reasons the World Health Organization (WHO) (prompted by the World Health Assembly) through initial discussions in 1970 introduced the dialogue which was designed to develop a basis for the availability of the right medicines, which were cost effective and could assist in the choice and access issues, mentioned above. Initially the WHO in the discussions suggested that certain drugs could be assembled in a list, which was later referred to as the Essential Drug List (EDL) (it was proposed that such lists could be different from country to country, dependent on the individual countries requirements). These proposals were adopted and since the initial introduction of an initial Essential Medicines List in 1975-1977 the WHO have continued to regularly (every 2 years) update the list, based on

evidence based decisions. Alongside the EDL the World Health Assembly agreed that the WHO should extend their work into organization issues and provide assistance in organizational structure which would bring together a number of management structural aspects for improved efficient pharmaceutical services in a country. The first of these was to set out the initial outline of the areas which could be considered to form the basis of a well-organized pharmaceutical policy which could cover the majority of areas associated with the pharmaceutical structure to the government and the public, through what would eventually be called a National Drug Policy (NDP), (WHO, 2001).

These proposals included discussion of responsible monitoring, evaluation and development of drug policies. A NDP would assume responsibility for all issues regarding essential drugs and their use. It was suggested this mechanism could also be responsible for setting training standards for the health professional workforce in order to ensure the appropriate use of medicines at safe and efficient dosage by introducing a NDP (WHO, 2001).

Its implementation would also provide a framework of clearly defined and thoroughly researched legislation and regulatory standards to ensure the appropriate access, quality and distribution of the Essential Drugs (WHO, 2001). In addition it was proposed that implementation of a NDP could offer important financial and political benefits through the regulation of the pharmaceutical market thus reducing financial speculation and individual gain against the common good for a country.

This research study focuses on discussing the importance and need for a NDP for Kuwait and how it can help in supporting development of the healthcare system in the country. Furthermore, it has been shown in this study that there are a number of areas where the introduction of a NDP could lead to improvements in the operation and control of the Kuwait regulations and processes. The rapid rise in the cost of medicines in the country year on year is also of concern. It is proposed through the evidence gathered in this study that Kuwait could benefit substantially

in terms of improvements in healthcare and control of quality, safety and efficacy of medicines if Kuwait was to introduce a national drug policy. It is also shown that there could be better control of financial outlay on medicines Presently, Kuwait does not have a NDP and the content of this thesis is promoting the importance of the development and introduction of a NDP.

In this study, Chapter 2 begins with a description of a NDP: its definition, composition, general goals and objectives, also the major components, formulation and structure. Furthermore, in this chapter some examples of NDPs in other developing countries are given and the resultant benefits from implementation. In Chapter 3, the aim, objectives, methodology and methods of the thesis are developed. Chapter 4 presents the analysis of interview data and results. The pharmaceutical sector in Kuwait is presented in Chapter 5, and in Chapter 6, the discussion of the study results from the interviews and the observations from the visits to the facilities; and in Chapter 7 a number of recommendations are made. Finally, a further proposal for the introduction of a Kuwaiti NDP is presented in Chapter 8.

# Chapter 2.0: Background

## 2.1 Understanding the concept of a National Drug Policy:

### 2.1.1 The definition of a NDP

In the proposal the precise definition for a National Drug Policy is suggested to depend on the regulatory needs, priorities for the health care system, various goals and objectives for each country. But the common definition for the National Drug Policy which was proposed, is “It is an authorized written statement set by the government, giving information, guidelines, goals and responsibilities for the pharmaceutical sector, whether public sector or private sector which plays as a guide for action and a commitment to a goal" (Brudon, et al., 1997). Therefore it presents a common frame work to set and identify the main strategies for the pharmaceutical field to reach and realize the health for all, and it should be developed throughout time. (Brudon, et al., 1997)

In addition Burdon and co-workers suggested that the NDP is able to assign roles and responsibilities to various parties involved in the medicines provision process thus giving the opportunity to improve efficiency. In this respect it is possible to ensure that all aspects of access to Essential Medicines can be effectively monitored and regulated (WHO, 2003). It was also proposed that a NDP could go hand in hand with a general National Health-care System.

These two organisational structures (NPD and a Health-care System) are considered to influence each other since a NDP requires an established National Health-care System in which to function, while a Health-care System can experience significant improvements by the strict and organised legislation and regulatory structures of a NDP.

An NDP is thus suggested to be a guideline or set of principles which can be used as an organisational reference text for health professionals in matters of drug usage and preventing any possible harm from improper use of drugs. An NDP can be a wide ranging organisational proposal which could include within the system medically/pharmaceutically based laws, specified courses of action, regulatory

measures relating to usage and financial priorities regarding drugs which are published or regulated by any government agency or their representatives (Kilpatrick, 2000). It was considered that the essential parts of a NDP would comprise of: Recognition of therapeutic requirements; Priority selection of essential drugs; Assurance of medicines quality; Drug supply and a distribution system; Effective legislation and regulation; Human resource development; and Dissemination of drug-related material (Gerald, 1991).

### 2.1.2 Composition of a NDP

An NDP is normally an official government statement (developed by the Ministry of Health) in presentable form which acts as a formal document for Aims, Decisions and Commitments regarding medicines. It can be suggested that in the absence of such a policy it is unlikely that there will be a general overview for the actions required leading the chance of conflicts among various government guidelines, due to unavailability of clear definition of goals, guidelines and their correct interpretation. (Hoebert et al., 2013)

Apart from the organizational aspects of the NDP, the Policy is normally based around the choices resulting from countries Essential Medicines List and the development of access to these medicines which can result in them being utilized to their highest potential. By deciding to have in place a list of Essential Medicines it forms a major part of health care, through medicines availability, affordability and cost effectiveness and other associated issues. It is known that the cost of medicines forms the main expense of the health budget within the pharmaceutical field. Part of the expense however can results from the initial purchase of poor quality of the medicines, inappropriate or irrational use of the medicines, and lack of access to essential medicines and wastage of medicines. It is also suggested that a NDP document is required to develop a platform for the discussions on the topics relating to drugs and pharmaceuticals (Hoebert et al., 2013).

It is possible to abbreviate the main needs of the NDP into:

- Presenting a record of aspirations, aims, value, and decisions of Government commitments;

- Defining National goals, objectives and priorities for the pharmaceutical sector,
- Identifying strategies to meet the objectives and identify the various factors responsible for implementing policy components;
- Providing a forum for discussions.

### 2.1.3 Main Goals and Objectives of a National Drug Policy

From these abbreviations, the goals and objectives of a NDP as proposed by the WHO are:

● To ensure the availability, affordability and accessibility of the essential drugs for the largest number of patient at all times.

● To promote the rational use of medicines.

● To make available and to use drugs which have quality, are safe and effective.

This leads onto the meeting of other national goals such as; improving national health, drugs manufacturing and handling at an economic level which effects directly nationwide services, and develops improved professionalism of the work (Reuter and Caulkins, 1995). But as indicated earlier a NDP revolves around the essential drugs concept which suggests that there should be consideration of a limited number of clinically recommended drugs which can thus lead to improve rational use, distribution and cost (Strang et al., 2012). The simplicity of dealing with fewer therapeutic agents can also facilitate easier training of health professionals, better quality assurance, procurement, storage and distribution.

But as indicated above in establishing the common goals and objectives of a NDP there will be differences from one country to another according to the needs, elements and requirements of each country. But even though the actual medicines will vary in respect of the needs of a country, in introducing an NDP the major objectives are to provide availability of the designated essential drugs to the population at affordable cost and without any discrimination and at the same time addressing quality, and safe and efficient use of all the medicines. As a result it focuses on implementing the practices for therapeutic levels and cost effective

medicines usage by patients and health service providers resulting generally in reduced numbers of medicines prescribed (WHO, 2001).

However in establishing the common goals and objectives of a NDP, it is accepted in the WHO guidelines that there will be differences from one country to another according to the needs, elements and requirements of each country. Based on the information above, it is proposed that the Kuwaiti Government should set the main goals and objectives of a NDP according to their needs before establishment of the organization.

Major components of a NDP with respect to the objectives attained are listed below in Table 2.1 which shows that most of the components are not restricted to one objective only (WHO, 2001).

It can be proposed that the most important objectives of a NDP are:

- Access: equitable access and affordability of essential medicines;
- Quality: quality, efficacy and safety of all medicines;
- Rational use: therapeutically sound and cost-effective use of the medicines by health care professionals and consumers.

Although the specific goals and objectives of a policy will depend heavily on the situation of a country, political priorities should be aligned to the National Health Policy.

**Table 2.1 Components of a NDP, linked to key policy objectives (WHO, 2001)**

| Components: \ Objectives: | Access | Quality | Rational use |
|---|---|---|---|
| Selection of essential drugs | X | (X) | X |
| Affordability | X | | |
| Drug financing | X | | |
| Supply systems | X | | (X) |
| Regulation and quality assurance | | X | X |
| Rational use | | | X |
| Research | X | X | X |
| Human resources | X | X | X |
| Monitoring and evaluation | X | X | X |

X = direct link; (X) = indirect link

2.1.4 The structure and basis of a NDP

The WHO (WHO, 2001) has suggested that the structure of a NDP can be considered to be tree like, consisting of roots, trunk and fruits. Initially when they are available, a strong and well-established roots system would consist of such as: the stakeholders of the government, media, consumer, health professionals, schools and universities and pharmaceutical industries. This can then lead to a strong broad trunk that consists of fundamental major points such as: monitoring and evaluation, human resources development, economic strategies for drugs, rational drug use, quality assurance, supply management, selection of drugs and legislation and regulation. It is then proposed that if the roots and trunk are good the tree will bear effective and mature fruits such as medicines needs for patients, which are safe and effective, rationally prescribed and dispensed, provide value for money, be affordable essential drugs and thus provide better health for all (WHO, 2001). The tree structure of a NDP suggested by the WHO is summarised in Figure2.1.

Therefore overall it can be strongly suggested that having a NDP in place is very important to a country, in terms of providing appropriate cost effective quality medicines when the patient needs them. But in producing an efficiently run system

with an NDP there is a dependence on many factors to be effective (Gerald, 1991). The requirements involved in setting up an NDP are therefore various in each country, and concerns the circumstances of the country, the political priorities, the economic situation, the level of health services and the extent to which there is government support for health care. As indicated above there are many reasons for needing the NDP, of which the most important include it:

- Provides official documentation on aims, objectives, decisions, responsibilities and ambitions which provides an insightful outlook for the government.
- Helps the global and local pharmaceutical sectors to know the main goals and objectives of a country.
- Identifies the strategies and studies needed to meet these objectives and identifies the various factors responsible for implementing the policy.
- Enables the pharmaceutical sector to ensure the availability and affordability of appropriate essential drugs.
- Provides a national forum for discussion and gives the opportunity to look for the problems which relates to pharmaceutical sectors, the public and the private sector (Gerald, 1991).

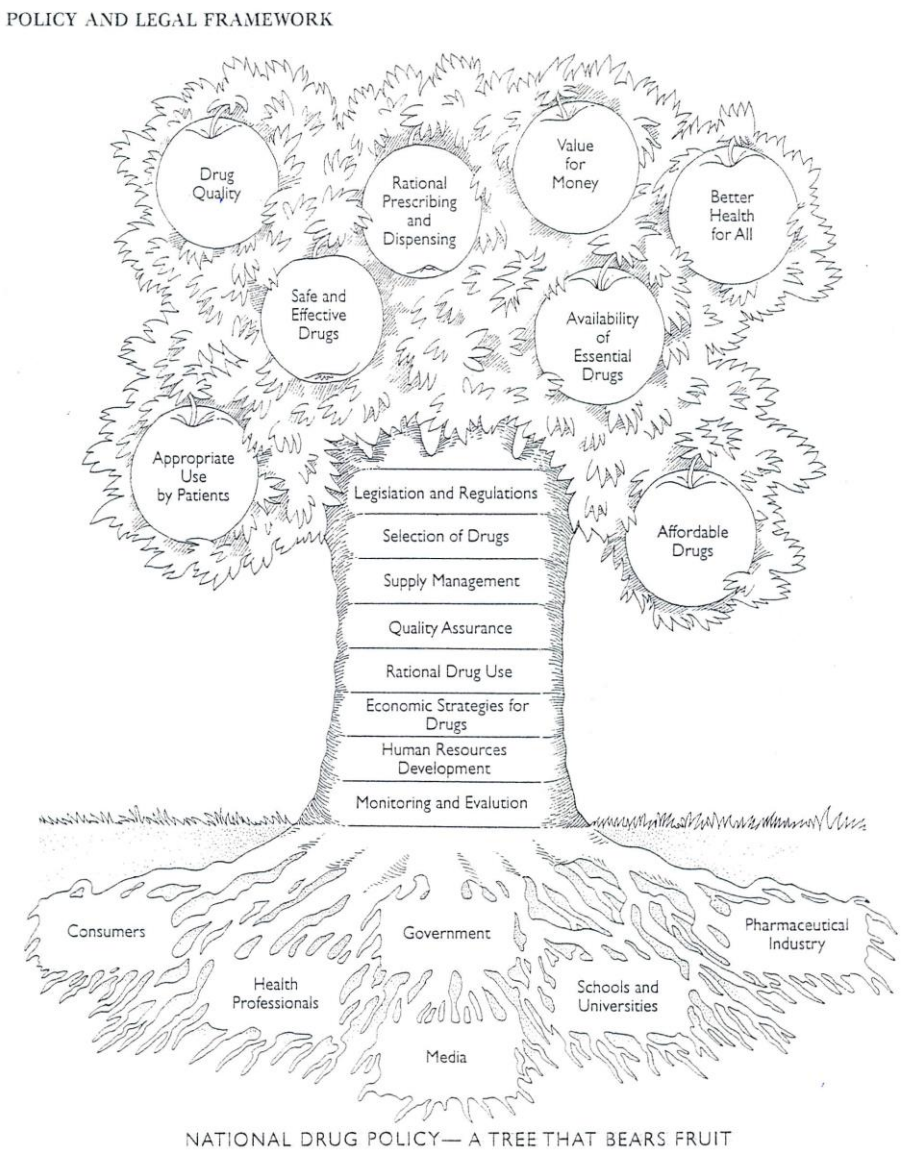


**Figure 2.1 National Drug Policies - A Tree That Bears Fruit (WHO, 2001)**

## 2.2 The formulation of an NDP

The process by which a NDP comes into being should be based around three major parts namely: the ‘development process, implementation and monitoring’ (Reuter and Caulkins, 1995).

The ‘development process’ is normally the first step taken and it aims to formulate the actual content of the NDP. This process is then followed by implementation of the policy aiming to achieve the objectives defined earlier through appropriate actions. The stage also includes the design of a long-term implementation plan, which typically could take between 3-5 years, and aims to ensure the steady progress of the policy implementation over time. In this plan the roles and responsibilities of all parties involved can be generally defined. These may include other government/association branches such as authoritative committees concerned with educational, trading and industrial development. In addition this stage would also involve health care professionals, pharmaceutical industry representatives, higher education/academic institutions, non-governmental organizations (NGOs); insurance companies associated with health care coverage and consumer committees. In bringing all these groups together it is considered very important to have a high degree of consultation and cooperation within these aspects in order to ensure that all sectors involved remain unaffected by the reforms necessary and that their concerns and their needs are met. This process has been shown to be extremely helpful in minimizing opposition to the significant alterations that the introduction of a NDP brings. In the final stage, the effectiveness of the measures taken and the results of the process should be monitored to ensure successful policy implementation and to correct any discrepancies (WHO, 2001). These major stages in the formulation of a NDP are summarised in Table 2.2.

**Table 2.2 Formulation stages of National Drug Policy (adapted from WHO, 2001)**

| | |
|---|---|
| **1. Policy process organization** | Appropriate national authorities initiate the development process identifying the policy objective and priorities as well as the parties involved and the resources to be used. Consultation with the WHO at this stage of the process is important. |
| **2. Problem identification** | A team of experts with prior experience in formulating drug policies at an international level perform an examination of the situation to identify the problems that implementation of a drug policy might be faced with and make appropriate recommendations to overcome these obstacles. |
| **3. Situation analysis** | Following problem identification, a thorough situation analysis has to take place in order to diagnose the cause of these limitations and identify appropriate strategies to guarantee the successful implementation of the drug policy. |
| **4. Definition of priorities to achieve goals and objectives of NDP** | Based on the situation analysis, priorities and strategies are set and decisions are made to deal with the most important problems. |
| **5. Preparation of NDP** | Having decided on the priorities and approaches towards tackling the major problems, the official policy document is drafted to clearly and formally introduce the principles, objectives and strategies of the NDP. |
| **6. Revision of NDP** | The policy document is subsequently subjected to a thorough revision with the participation of representatives from all sectors and authorities involved and corrections/improvements are carried out leading to a finalized version of the NDP document. |
| **7. Formal endorsement of NDP** | The completed NDP document should then be formally endorsed by the local authorities/government. This is of crucial importance in order to demonstrate the political will and commitment to the implementation of the drug policy. |
| **8. Launch of NDP** | Success of the policy depends widely on the commitment of the parties involved to the policy objectives and also on the promotion of the policy and education of the consumers/general population. |

## 2.3 The major components of NDP

### 2.3.1 NDP components

As has been indicated above a NPD is comprised of a wide range of components, all of which can be considered to possess important roles in achieving the principal objectives of the policy. The main components are proposed to be: selection of essential drugs, affordability, drug financing, supply systems, regulation and quality assurance, rational use, research & development, human resources development and finally monitoring and evaluation (Webb, 1999).

### 2.3.2 Selection of Essential Drugs

In choosing drugs which can appear in the Essential Drugs List for a country, it is important to determine in the Government Policy, established by the Ministry of Health, priorities for both the public sector and the private sector, and specify the appropriate need of the drugs and their adoption for the essential list. Also, it is important to define the procedural requirements for defining a drug and its formulation in the Essential Drugs List and the basis of the selection criteria for traditional and herbal medicines (Hogerzeil, 2004; Laing, 1991).

Initially, one of the main aspects which should be considered is the importance of the Essential Drugs List. In all countries which have introduced a NDP the importance of considering the basis and differences in the origins of the populations should be taken into account, for aspects such as indigenous health issues, their immigration status, and their rights to access to medicines, based upon the rules of a country. Different population requirements and resources are likely to place different demands on the healthcare system, and may have a bearing on the procurement choice in the initial decision stages of medicines choice are most important. Accordingly, the Essential Drugs List can help to set priorities in the NDP and promotes equity in that a small number of well-established drugs (and associated dosing regimens) can form a central position in the policy. These are the medicines that are most commonly required in the population and can be the most cost-effective way to treat pathologies of

relevance. Having a smaller list of essential drugs can also be important for physicians and patients who want to have a clear understanding of what is being done and what is available (Morgan et al., 2008).

These common – essential – drugs tend to be present in many or in all countries NDPs and assist in ensuring a reliable, low-cost supply is always available both locally and globally. The WHO argues that buying large numbers of drugs in purchase orders results in better price competition and economies of scale (Morgan et al., 2008). Quality assurance, purchasing, storage, distribution and legislation can all be simpler when a smaller number of drugs is involved, further demonstrating the importance of an Essential Drugs List (Who, 2003). In this respect, maintaining an Essential Drugs List can save money for the country when it comes to medicines procurement and ensures a steady supply of medicine.

However, the Essential Drugs list is only one aspect of a NDP, albeit an important one. The availability of drugs is not much use without the correct and safe means by which to use them. In fact, their incorrect use can be fatal, and appropriate safeguards need to be in place to prevent inappropriate use. It is therefore essential that drugs have to be regulated to ensure patients receive a benefit and not a problem; this is a central aim of a NDP.

In short, the availability of an Essential Drug List in Kuwait is likely to support the Kuwaiti Government in determining the appropriate need of drugs, reducing the number of expired drugs in the Central Medical Store and savings of the general budget. This is especially as the government purchases around 1100 to 1350 pharmaceutical products (drugs, injections and medical consumables) yearly (KMOH, 2016), and the establishment of an Essential Drug List would support the vision for a long term programme for the specific needs of these products. Furthermore, the introduction of an Essential Drug List as part of the NDP could contribute to the promotion of the rational use of medicines and ensure that the procured drugs meet the needs of the health care system in Kuwait.

### 2.3.3 Affordability

The important factors in establishing the drug affordability are the commitments of the government, to: pricing policies; tariffs and distribution margins; reduced drug tax rates; multi-source product promotions for increasing the competition in generic goods; promoting generic policies for product exchange which should entail good procurement practices; the therapeutic replacement for a single source product; price negotiations; the position of Trade–Related Intellectual Property Rights (TRIPS), to include the introduction of complaint measures, the recognition of the basis for patented drugs and their compulsory licensing should be discussed in the documents (Morgan et al., 2008).

### 2.3.4 Drug financing

Appropriate medicines financing aims at ensuring efficiency in medicines use with limited wastage, where the financing should include special privileges for the needy patients, and address increased funding requirements for priority diseases as proposed by the Ministry, and from government (WHO, 2001).

The Kuwaiti Government has given considerable financial support, (as will be shown later in the Thesis), to its healthcare system and it is keen to increase the volume of spending in this area in order to keep pace with population growth in the country and to prevent any shortage in the level of healthcare, whether in hospitals, health centres, medical equipment and medicines. But it also has acknowledged that there needs to be some form of overall control of expenditure which is increasing considerably year on year. This is illustrated in Table 2.3, the annual health budget allocated to the Ministry of Health from 2004 to 2015 is shown.

Through an analytical study which examined the budgets of the last five years, it has been shown that the budget is increasing and will reach 1.548 billion USD in 2019/2020. However, it was proposed that part of the increase in the budget in this sector is related to the increase in the population, and the incremental needs to cover the increase of medicines and increase in related medical materials prices. See Table 2.4.

**Table 2.3.The general budget of the Kuwaiti Ministry of Health from 2004 to 2015 (KMOH, 2015 a)**

| Fiscal Year | Lab. Materials (Million USD) | Medical Consumables (Million USD) | Drugs (Million USD) | Total Amount (Million USD) |
|---|---|---|---|---|
| **2003/2004** | 28,290 | 42,438 | 131,356 | 202 |
| **2004/2005** | 27,647 | 41 | 133,462 | 202,215 |
| **2005/2006** | 37,400 | 44 | 166 | 247,400 |
| **2006/2007** | 43,350 | 59,231 | 176 | 278,500 |
| **2007/2008** | 48,851 | 61 | 184,856 | 294,693 |
| **2008/2009** | 74,594 | 77,400 | 250,300 | 402,253 |
| **2009/2010** | 63 | 86,314 | 315,835 | 465 |
| **2010/2011** | 65 | 88,552 | 325,233 | 478,733 |
| **2011/2012** | 93 | 119,332 | 507 | 719 |
| **2012/2013** | 86,933 | 125,958 | 465,131 | 677,873 |
| **2013/2014** | 89,618 | 152,267 | 606,471 | 848,358 |
| **2014/2015** | 113 | 200,676 | 697,907 | 1 Billion |

**Table 2.4 Five years forecasting for the health budget in Kuwait by using time series analysis**

| Fiscal Year | Lab.Materials | % | Medical Consumables | % | Drugs | % | Total Amount |
|---|---|---|---|---|---|---|---|
| **2015/2016** | 169,689 Million USD | 15% | 218,817 Million USD | 19% | 744.991 Million USD | 66% | 1,135 Billion USD |
| **2016.2017** | 185 Million USD | 15% | 238,534 Million USD | 19% | 812,122 Million USD | 66% | 1.237 Billion USD |
| **2017/2018** | 201 Million USD | 15% | 258,718 Million USD | 19% | 880,142 Million USD | 66% | 1,339 Billion USD |
| **2018/2019** | 216 Million USD | 15% | 279,144 Million USD | 19% | 948,170 Million USD | 66% | 1,443 Billion USD |
| **2019/2020** | 231 Million USD | 15% | 300 Million USD | 19% | 1,017 Billion USD | 66% | 1,548 Billion USD |

Based on last 5 years experience

In Table 2.3, the increasing amount from the budget which is allocated for the purchase of medicines, medical consumables and the associated laboratory materials in each year shows that the Ministry of Health is keen to provide the necessary medicines and medical supplies and has taken into account the medical cost of the increase in the population and the numerous modern developments in medical and pharmaceutical services.

### 2.3.5 Supply systems

In establishing an efficient NDP, an efficient medicines procurement scheme and a reliable supply system is an important factor for access to Essential Medicines as it can provide a balance between the country's needs, over and under supply, efficient procurement practices and having medicines available at the appropriate time in a yearly cycle. It can also provide a balance in the private and public system in supply and distribution structures. Associated with these processes it can lead to preventative actions for theft control and corruption, improved inventory control and prescribing methods for waste or expired drug disposal and measures for meeting acute emergencies (Yusuff and Tayo, 2004). In terms of the organizational structure, the establishment of a NDP in Kuwait could also assist in giving an improve structural basis on which the KMOH can examine whether changes are required in the procurement system for medicines brought into Kuwait and the associated supply management system. By closer identification of the appropriate selection of drugs this could lead to providing a possible improved cost effectiveness and overall reductions in expenditure within the national budget.

### 2.3.6 Regulation and quality assurance

It is normally the case that part of the function of the Ministry of Health's Drug Regulatory body is to establish and enforce legislation and policies on the pharmaceutical sector (which includes many aspects of provision, adverse drug reactions of medicines and supply of medicines to the patients of a county). The Drug Regulatory Authority (DRA) is the agency appointed by a government to ensure that the research, manufacture, procurement, import/export, distribution, supply, marketing and sale of drugs adhere to specified and strict standards (Ray and Stein, 2006).

Also it is to ensure there are records which provide accurate information about quality matters related to products, which can guarantee their authenticity (to include being free from counterfeiting) and safety. It is normally suggested that the groups involved in medicines provision (agents, wholesalers and manufacturers) should be transparent and independent in their working and their relations with Ministry of Health and should not be biased. It is suggested to be the case that a

NDP will clearly state the measures which should be taken to define the processing steps for drug registration and evaluation.

Normally the Ministry of Health within the Government should ensure an efficient legal framework for regulation and adequate manpower and financial support. The DRA in the regulations associated with the Health Policy would normally provide the written basis for commitment to medicines procurement from: outside a country to include good written or inspection processes; and where medicines manufacturing occurs good manufacturing practices (GMP) approaches. The Policy should also state the basis of law enforcement; drug control facilities; and regulated drug promotion methods, also make reference to working guidelines for herbal and traditional medicines. As the NDP develops it is likely that checks for effective pharmacovigilance would be developed for monitoring for possible adverse reactions from drugs and that there would be a joining with International Databases which deal with promotion of international exchange of drug related information (Ray and Stein, 2006).

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Therefore Drug Regulation is an important component of a NDP. As a result much attention is often paid in a country to developing an efficient system and to providing adequate regulation.

It is proposed that the DRA should operate independently and with a transparency in order to provide an unbiased support service. The agency should have access to steady funding, be in regular contact and working in cooperation with external experts and international organisations. It should also have quality control facilities at its disposal and a reliable system of law enforcement (WHO, 2001). In carrying out their work, one of the key functions of the DRA is to establish drug registration. The main stages of the drug registration process are shown in Table 2.5.

This current study will discuss later (in Chapter 6) the effects of a NDP on medicines and organizational quality assurance in Kuwait, namely how to investigate the basis of regulations and legislations and the potential for introducing Quality Assurance Departments in the MOH Administrations and Hospitals, and

whether there would be an advantage in establishing a Pharmacovigilance Centre in Kuwait.

**Table 2.5 Stage of drug registration (adapted from WHO, 2001)**

| | |
|---|---|
| **1. Notification procedure** | The procedure does not examine the safety, efficacy and quality standards, but instead focuses on providing standard information about all the drugs available in the country. |
| **2. Basic authorization procedure** | Licensing of drugs through assessment of efficacy, safety and quality, by the DRA itself or based on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. |
| **3. Full registration** | Evaluation of the data regarding a pharmaceutical product prior to marketing authorization and determination whether this product would be branded as a prescription drug. At this level the drug registration should be reviewed regularly. |
| **4. Re-evaluation of older drugs** | Reassessment of already available products and renewal or revocation of license according to clinical guideline updates. NDPs usually impose a limited registration period (~5 years). At the end of this period drug registrations and licenses have to be re-submitted and re-evaluated. |

### 2.3.7 Rational use of Drugs

In terms of prescribing a medicine for a patient it is implied that suitable drugs should be in the correct dosage, for the clinical needs of the patients and that this is addressed in an efficient manner and at the right time and lowest possible cost to meet the health issues. However in practice, many aspects can affect the rational prescribing of drugs. These can include the wrong drugs for the patient condition, the wrong formulation or strength, drug-drug interactions, inappropriate dosage for the patient (e.g. children) Common problems in prescribing inappropriate drugs can be overcome by strict regulatory interventions and promotion of rational drugs use. To achieve these objectives there is a need to

bring into operation ‘evidence based guidelines’ to assess the value of a particular medicine for clinical activities as a first step towards training, utilization reviews, and supply of drugs. (Ratanawijitrasin et al., 2001; Song et al., 2014)

There is also the need of training programs for informal drug sellers and provision of unbiased drug information, educating consumers and provision of control and monitor of Ministry of Health (MOH) over the health professionals who working in private sector and implementation of managerial strategies. All of which are key issues to enhance rational drug use (Ratanawijitrasin et al., 2001; Song et al., 2014). (This aspect is discussed more fully. later in Chapter 6, Page 300)

### 2.3.8 Research

Operational research is generally considered in many fields to be an important mechanism for assessing the policy impact on national systems, and in this field it is useful to determine the economics of medicines, prescribing practices and the methods of dispensing drugs, in both the work and socio-cultural environment (WHO, 2001). It is suggested to be of help in evaluating various drug related scenarios and monitoring and implementation of policy developments for drugs. It has also been used in the field of clinical drug research (WHO, 2001).

### 2.3.9 Human resources development

In a successful health system fully trained staff is extremely important to provide an efficient functioning facility and for this reason HR policies are regularly designed around addressing issues which relate to ensuring the availability of trained, skilled and motivated individuals for health policy implementation and to avoid failure of the proposed policy objectives. It is agreed that in the health field that governments (through the MOH) are liable for overseeing and planning for the emerging needs of training the manpower for the pharmaceutical/health sector in a country. Career plans and team building activities are often central to this training and pharmaceutical/health staff across the many disciplines is normally employed after fulfilling the minimum qualification and training requirements in the specific category (Schneider et al., 2006).

The possible need for human resource development and training programmes for health professionals in Kuwait are discussed in detail in Chapter 6. In addition, there is discussion of studies on whether the NDP can lead to possible changes in personnel development, training and the development of job satisfaction and work performance. If these aspects were to be examined, then it is proposed that there may be an increase in professionalism and efficiency of the health service workforce.

#### 2.3.10 Monitoring and evaluation

In any of these developments there is a need to monitor the success of outcomes of human resource development and in the monitoring and evaluation of the pharmaceutical/health sector developments. As a result it is proposed in the WHO documents that there should be some form of compulsory commitment from the MOH regulatory authorities for drug monitoring and evaluation using some form of assessment, such as, standard indicator-based surveys and their evaluation for impact analysis on whole health system and effectively the economy (Abdollahiasl et al., 2014).

## 2.4 World Health Organization and NDP

As has been suggested above it was proposed at the World Assembly meeting that every human being has the fundamental right of the highest standard of health without any discrimination of religion, race, political view, economic condition or social status. In this respect the access to Essential Medicines plays a crucial role in increasing the standard of living of the individual along with food, clothing, housing, and what could be considered necessary social services. As has been indicated earlier, in developing countries drug costs account for a very large share of the total health budget, but the outcome of spending such large sums does not guarantee that the appropriate medicines will be available for all of the population. In addition the problems for a developing country in providing treatment for its people is accentuated by the inability to provide appropriate and sufficient

medicines to deal with traditional diseases like tuberculosis and malaria and other tropical diseases alongside newer diseases, such as diabetes, heart disease through obesity and AIDS and increasing drug resistance for the important antibiotics which has all led to increased pressure on health resources and increased spending on drugs.

Over the last 40 years, pharmaceuticals have played a vital role in reducing global morbidity and mortality. But, just as medicines are one of the highest government budget costs, they are also very high in household expenditure in many developing countries. The WHO has estimated that one-third of the world's population needs access to essential drugs (WHO, 2001). Over these 40yr the WHO has worked with numerous countries to try to achieve the aim of access to essential drugs and medicines, and in improving quality and safety of medicines and to work with countries and other agencies to improve the rational use of medicines.

In order to achieve these improvements it is considered essential in the advice given by the WHO and other agencies that all countries should formulate and implement a suitable NDP (WHO, 2001).

**Table No 2.6: National drug policy components related to the key policy objectives**

| **Components:** | **Objectives** | | |
|---|---|---|---|
| | **Access** | **Quality** | **Rational use** |
| Selection of essential medicines | √ | (√) | √ |
| Affordability | √ | | |
| Financing options | √ | | |
| Supply systems | √ | | (√) |
| Regulation and quality assurance | | √ | √ |
| Rational use | | | √ |
| Research | √ | √ | √ |
| Human resources | √ | √ | √ |
| Monitoring and evaluation | √ | √ | √ |

√ = direct link; (√) = indirect link

**National Drug Policy:**

As has been shown in earlier sections the WHO have had a major part in proposing the basis for an NDP. The initial function of the WHO, when established back in the 1970s was to provide considerable attention to ensuring the saving of lives by improving health in all regions of the world. This is carried out through advising on procedures and the establishing of structures which can assist in the improvement in access to drugs, which was followed up by a request to suggest the basis for an initiative in Essential Medicines/Drugs. In addition advice was developed in providing the basic outlines on how to improve the quality of drugs. As the portfolio grew the rational use of drugs became an important area for the WHO and their involvement has grown into advice in Developing Policy and into Pharmacovigilance. Because of the basis of the development of the WHO is through the World Health Assembly the organization is keen on establishing international norms and standards for pharmaceutical products, through encouraging and supporting the WHO member countries to establish develop and implementation medicines policies and in particular an NDP. (WHO, 2001)

The establishment of a NDP is however considered to depend mainly on the will of a National Government to provide the support and assistance, which will involve financial or administrative support. In this respect the Government with the MOH will play the most important part in the process by cooperating with several Government agencies including the MOH, the Ministry of Finance, the Ministry of Trade and Industry, Universities and other government bodies. In addition in establishing a NDP there should be involvement of the private and public sectors to include pharmaceutical industries, associations, companies and pharmaceutical agents and notification to all other agencies which are related to Medicines. In order to assess the success of the NDP developments the WHO and MOH have shown that they could sight clear results which demonstrated the advantages to health and the organization of the function of obtaining and using medicines linked into a developing NDP framework between all the partners and by the end of 1999,

over 100 countries had NDP in place or under development, see Figure 2.2. (WHO, 2000)

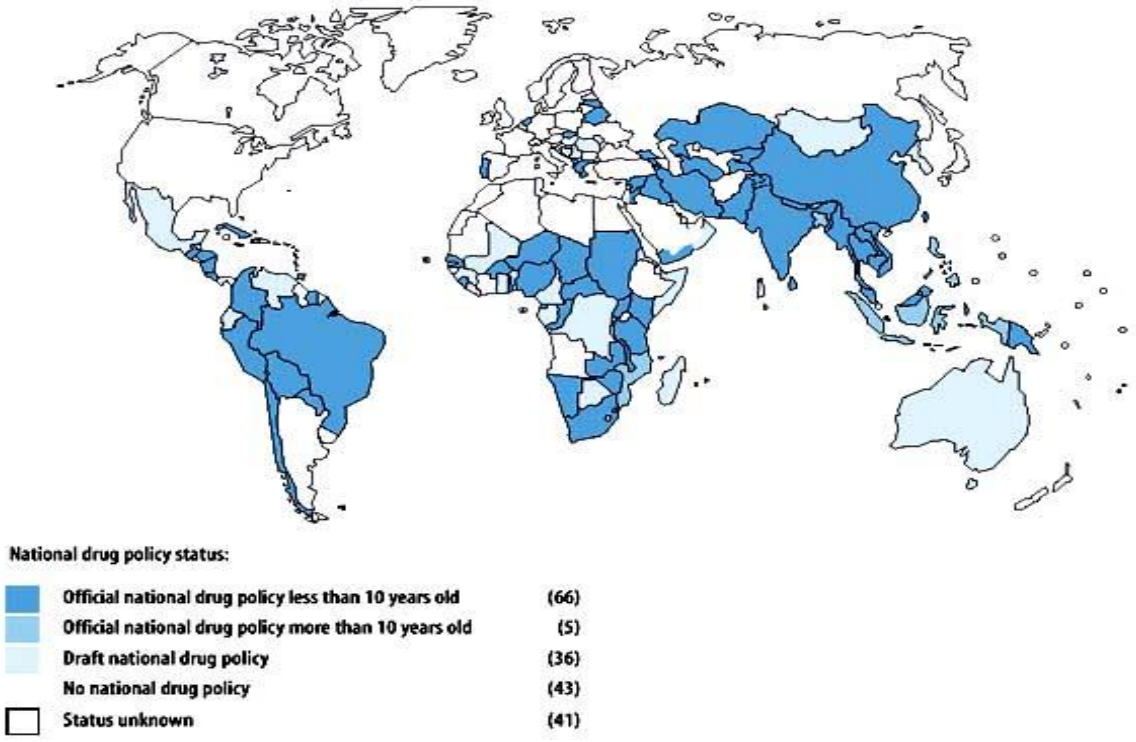


**Figure 2.2. By the end of 1999 over 100 countries had National Drug Policies in place or under development**

Typical examples of the support work done by the WHO in this area was demonstrated by the establishment in the late 1990s of a program designed to help its member states, in the Eastern Mediterranean regions to develop, implement, monitor and to evaluate their National Drug Policies. The core concept for this program was to attempt to solve the pharmaceutical issues, by training staff in the MOH in following the WHO guidelines on each step of the policy process through consultative meetings between the WHO and the countries involved.

The first meeting was in September 1998, in Alexandria, in Egypt which focused on drug policy development, priority setting, implementation strategies and indicators for evaluation.

The second meeting was in Tehran, in the Islamic Republic of Iran, in December 1999, and concerned rational drug use.

Throughout the biennium between “1998-1999” the WHO project assisted 23 countries including Angola, Oman and India to develop their NDP’s. Other countries including Slovakia, Czech Republic, Romania and Uzbekistan also initiated the first stages of the process, and other countries like Kenya took advantage from these projects in moving from their theoretical policy forward to a practical policy by which their NDP is now implemented. The results of these efforts have also impacted on improving access, quality and rational use in these countries. See Figure 2.3. (WHO, 1999)

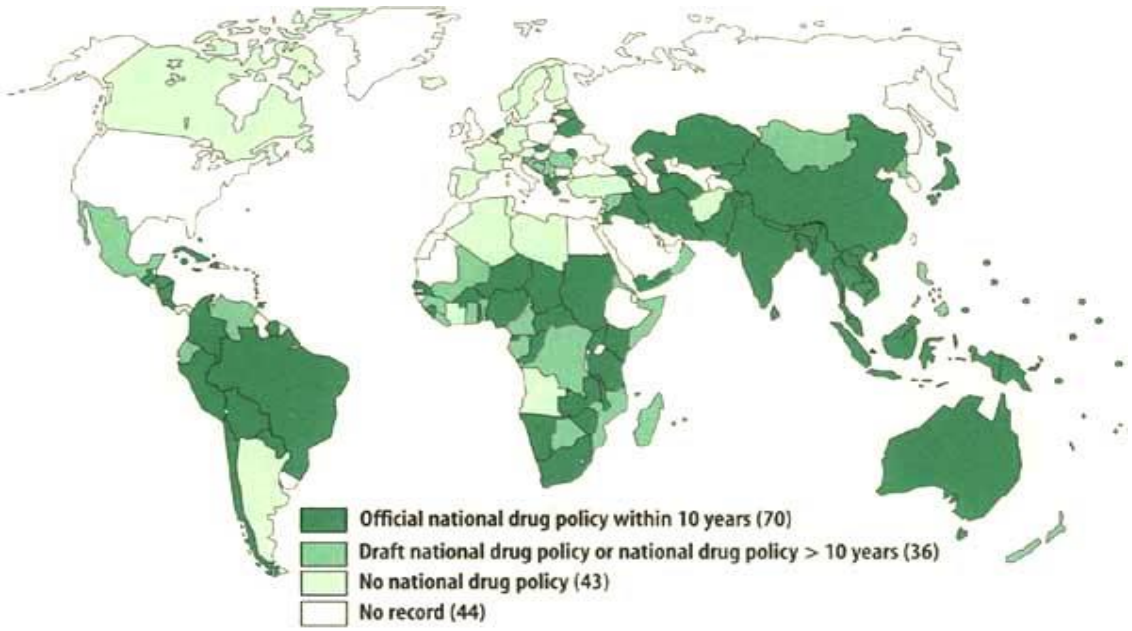


**Figure 2.3 Improvement access, quality and rational use - National Drug Policy 1999**

### 2.5 NDP process, implementation and regulation - Role of the WHO

As has been indicated above however, the development of a NDP is a complex process involving formulation of policy, implementation of strategic activities aimed at achieving policy objectives and monitoring. In order to organize and prioritize requires careful planning involving all the parties along with political dynamics is needed in order to achieve a successful National Drug Policy (WHO, 2002).

### 2.5.1 Planning

Prior to policy adoption, an implementation plan is required. The implementation plan defines action points, division of responsibility, estimates the required budget and gives indicative time frame (WHO, 2002). The plan and the process leading to the expected outcome make a NDP meaningful. The strategic plan used to develop the policy should specify various steps in the development process.

### 2.5.2 Involving all parties

As indicated it is important for consultation and negotiations to take place with all interested groups which would normally involve government bodies, non-governmental organizations (NGOs), professional associations, academia, international pharmaceutical industries, drug sellers, doctors, pharmacists, nurses and consumer groups and their involvement is regularly necessary throughout the policy process. In addition, consultation with the Drug Regulatory Administration (DRA), district and provincial medical and administrative personnel, traditional and herbal drugs practitioners and sometimes insurance companies would be involved. Also it may be appropriate to involve media and international organizations can also be of help in implementing the policy (WHO, 2002).

### 2.5.3 Political dynamics

As has been stated the formulation and implementation of a policy needs to have political authority and the participation because the aim of a policy is to achieve access to basic health care and development of a NDP is likely to require funding and changes in the regulatory framework. These changes transmitted within governmental areas will have to be proposed and a clear advantaged expressed to the other government officials outside of Health. Such advantages could be expressed by indicating that the pharmaceutical sector is likely to be more efficient and responsive to health needs. Strong political direction and sustained devolution are vital for the formulation and effective implementation of a national drug policy (WHO, 2002).

## 2.6 The steps of NDP process

Since the WHO established the proposal of a NDP, it has been promoted on the basis of having in place processes to ensure its effectiveness. The process of a good national drug policy should be built around the 3 main components of: 1). Development, 2). Implementation and 3). Monitoring and Evaluation (Chowdhury et al., 2006).

### 2.6.1 National Drug Policy Development

The majority of countries have formulated and subsequently updated their NDP. In a number of countries an emergency or an important political change involving developments such as the expansion of local industry or the implementation of a global trade agreement has often created an opportunity to start the process of formulating or adjusting a policy. The WHO has proposed a process for development of a NDP to support countries in identifying the work procedure of this project. But the development process suggested by the WHO is not channeled directly at countries, where, as mentioned before each state has its own priorities, needs, specificity and factors that determine the mapping of work on their project (WHO, 2001). The development process can include;

Step 1: Organization of policy process

It is suggested that the Ministry of Health would normally lead the process of formulating a NDP and organize the process of taking forward the development of the policy structure, its objectives and its priority components. An important part is to Identify the interested parties, necessary resources, donors, assistance from other support agencies, and outside agencies such as the WHO and to make contact if appropriate with countries who had relevant experience'

Step 2: Identify the main problems

To set realistic objectives an understanding and methodical analysis of the problems in the pharmaceutical sector is generally required. It is proposed that

expertise and knowledge is developed from gathering knowledge from experience gained from other countries and knowledgeable professionals. Also from other disciplines and backgrounds which, are gathered to examine the situation systematically, to identify the main problems which the country faces and make recommendations to overcome these issues. It is proposed that these issues and recommendations can be discussed at multidisciplinary workshops which help in formulating consolidated advice to the government

Step 3: Situation analysis

It is considered important to carry out detailed analysis of the situation in pharmaceutical sector before moving forward and then to undertake an analysis of the source of problems in order to identify potential solutions, and to choose and set appropriate strategies.

Step 4: Setting goals and objectives

After the identification of the main problems, goals can be set and priority objectives identified. This can start with discussions among key policy-makers and involve interested parties.. From these developments the discussion can become more detailed and can include more careful deliberation of the variations of interest and structural limitations within the existing system from which is important to set objectives and strategies which are attainable.

Step 5: Drafting the policy

After situation analysis and reference to NDP's from other countries the completion of the outline of the main goals, objectives and approaches can be addressed. At this stage small groups of professionals from different areas of the MOH and Drugs Regulation and other interested parties can be brought in and can be involved during earlier stages of the process and generally draft the policy.

Step 6: Circulating and revising the draft

The Draft Policy should then be circulated for comments from members of the Ministry of Health, and other Government Ministries and Departments, also

relevant institutions, and those considered having an interest in the private and academic sectors. Based on the comments received, after circulating the draft policy document, a further iteration of the NDP can be revised and finalized. Once a further draft is development, it is time for early discussion which will hopefully lead to in principle authorization by the government sectors responsible for planning, finance and education which is so important for successful implementation of the policy. However one aspect which is unlikely to be agreed at this time is the agreement of the budget at this stage.

Step 7: Securing formal endorsement

Once these stages are decided it is important that the Development of the Regulations is proposed and that only the enabling components of the policy are included into law. Without the operational details agreed as it may become difficult for future adjustment.

Step 8: Launching NDP

The next stage should be to launch the NDP which is one of the most important steps as it is important because the success of the policy depends on an early understanding by different sections of society and their support for the policy objectives. To assist with success the implication and benefits for all the interested parties should be clearly highlighted. In this respect knowledgeable professionals and opinion leaders can help endorse and promote the policy through a well-designed campaign. To ensure public understanding and support for the policy the media and a variety of other channels can play a major role in publicizing and making the policy availability to different target groups, (WHO,2001).

### 2.6.2. NDP Implementation

In order to attain success from the 8 stages above it is suggested that a carefully formulated policy is insignificant if it is not implemented through a “Master Plan”, which includes the main structural plan for establishing the NDP through identifying the main issues, requirement and needs of the health care system. Every component of a policy requires a detailed strategy and specific action plans.

#### 2.6.2.1 Priorities for implementation

However although the Steps above can be discussed within each country who consider the introduction of a NDP the priorities of each country can vary and hence the priorities of implementing the policy differ. For instance rational use and cost of medicines could be of concern in countries having broad health care coverage with no access issues. Therefore, implementation of a drug policy would normally be focused on regulating the market and the cost without affecting sustainable access and equity. In contrast the focus of the policy in least developed countries may be on increasing access to Essential Medicines. Prioritization of implementation in both cases could be decided by the severity of problems under consideration and the potential of achieving the objective with available resources and making a meaningful impact (Chowdhury et al., 2006).

#### 2.6.2.2 Master plan and work plans

From the NDP it is likely that there will be generation of an implementation plan which can illustrate the development structure for each component of the policy and indicates what needs to be done and who is responsible. At this stage it is possible to obtain some ideas about the required budget and a rough time frame associated with development and implementation, although overall the introduction of a fully operating NDP has in other countries taken around 5yr. By having an outline Master Plan it helps in instigation, operation, what should be communicated and monitored by all parties involved. It is suggested for proper execution, of the master plan that is should be divided into periods such as annual action and work plans then developed accordingly with the various agencies involved in its implementation. Approaches for each component, such as identifying the responsibility, the major tasks, and defining the target output, the time frame and the outline budget would normally be outlined in the plan (Chowdhury et al., 2006).

#### 2.6.2.3 Responsibilities in implementation

It is proposed that a co-ordination body designated by the Ministry of Health should supervise and coordinate all activities. They should monitor the implementation

process and the targets to be achieved. It is also considered to be important for national consultative forum to be created to maintain countrywide support, and to ensure that the major stakeholders are consulted and involved (Chowdhury et al., 2006).

#### 2.6.2.4 Financial resources

The matching of strategies and action plans with available financial resources is also important. Also it is indicated that it should be made clear what allocations will come from government funds, the contributions from international and local donors and the revenue generated from drug registrations and fees comprise the usual funding sources (WHO, 2001).

#### 2.6.2.5 Regional cooperation

In implementation of drug policies, it is also considered important that there are regional cooperation, skills, expertise and facilities in different countries, and what support can be given by institutions and organizations. It has been reported that cooperation between countries on a regional basis is increasing on a wide variety of policy and economic issues. It is proposed the greater harmonization in drug regulatory standards could results in a more economical use of resources.
A typical example of regional partnerships: are the Association of South-East Asian Nations (ASEAN), the European Union (EU) and the Organization of African Unity (OAU). (WHO, 2001)

#### 2.6.2.6 Technical cooperation with WHO

In addition to the support provided the countries and associations listed above, the WHO has previously provided an information exchange forum and further promote a cooperation through training courses and research projects. They have for some time helped to form professional networks, and provides training and research through collaborating centers, and also helped developing NDP’s by providing technical information and key documents.

In addition to all of these support areas there is regularly, the International Conference of Drug Regulatory Authorities (ICDRA) and also training courses which are conducted to discuss drug regulatory matters and drug policy issues (WHO, 2001).

### 2.6.3 National Drug Policy Monitoring and Evaluation

Once in place it is suggested that Monitoring and Evaluation is essential to ensure the program is progressing satisfactorily. This can occur through various methods such as:

1. Organization of the data collection.
2. Data collection procedure.
3. Analysis and reporting of the obtained findings.
4. Survey implementation.
5. Determination of the cost of the most important drugs.

The supervisory visits and routine and sentinel reporting which can be used for monitoring and reviewing the implementation of planned activities. The Monitoring and evaluation of a system is a constructive management tool that allows a continuous assessment of progress and also provides transparency creating a standard in comparison with other countries (Carr et al., 2007).

#### 2.6.3.1 Indicators for monitoring

Initially in carrying out the above it is important to determine the progress achieved and to set realistic and achievable performance standards or targets. Once that is completed indicators to measure changes can be selected and used to compare and assess whether the targets are being achieved. These indicators are required to be measurable, clear, valid and reliable.

Categories of policy indicators include: structural indicators, background information, process indicators and the outcome indicators. These indicators should be highly standardized so that trends can be identified.

Some of the important main indicators can cover the following aspects:

■ Having access to Essential Drugs, and other indicators on medicine financing schemes, and on public supply management; which can provide information on access to essential drugs;

■ Ensuring the function and efficiency of the quality control laboratory, regulatory authority, and handling of drugs to maintain the quality provide information about drug quality;

■ Evaluating the prescribing and dispensing of drugs should be done using a list of essential drugs and the clinical guidelines, which should provide drug use information patterns.

It is suggested that by using an indicator-based method of evaluating the pharmaceutical situation it can be useful for all parties involved in the pharmaceutical field. These studies and its results can provide clarity of the problems in the country so that Policy-makers, implementers and managers can reassess their strategies and priorities.

The results can also be useful to international agencies and donors to focus on the areas that require support and to determine the significance of investing resources in the areas in order to achieve best impact (Abdollahiasl et al., 2014).

#### 2.6.3.2 Multi-country comparative evaluations

It is also helpful during overall evaluation to include other multi-country studies, and international collaborations on policy issues which can assist national policymakers in learning about innovative approaches (WHO, 2001).

#### 2.6.3.3 Periodic evaluations

Finally after the NPD has been introduced and been in operation for a period of time, it is suggested that its working within the country should be evaluated periodically by professionals either from the country or from other countries or other agencies to monitor its continued development and also to suggest any improvements if appropriate (Abdollahiasl et al., 2014).

## 2.7 Examples of National Drug Policies in Operation in other Developing Countries

### 2.7.1 The introduction of a NDP in Developing Countries

Based on the previous sections, it is already clear that NDPs can be extremely useful for countries in the developing world in order to help them control drug use and improve healthcare conditions and public welfare. Assistance is also available to these countries from a number of sources and as an example the UK Government in recent years has taken steps towards collaborating with governments of the developing world. This included sending out a message of commitment to assist in improving access to essential medicines in countries of the developing world (DFID-UK, 2004). In this section, a few examples of countries that have benefited from the implementation of NDPs are mentioned below.

The perception of the importance of the NDP in the development of a pharmaceutical healthcare system has encouraged many developing countries to organize and structure the basis for their own NDP, such as recently in Sri Lanka (2015) and as a result, many Ministries of Health have established a belief in the importance of a NDP in developing the medical and pharmaceutical healthcare fields in both the public sector and private sector.

### 2.7.2 National Drug Policy of Ghana

There are now many Developing Countries that have establishing their NDP, and have used it in developing its overall health system. When doing this they have made efforts to deal with problem areas and found solutions, which can alleviate the problem areas. Once in place these countries have generally followed these up by continuously developing the NDP organization. It is proposed that the State of Kuwait should take note of the benefits reported from these examples and analyze these examples, especially where the country has discussed issues in these countries that are very similar to those issues in Kuwait. From this information the difference in aim, objectives, nature of work, factors and the specificity of each country has been taken into account.

As an example of recent discussions of NDPs', In Africa, Ghana had significant gaps in access to medicines despite the implementation of a NDP in 1999. Problems were related particularly to affordability of products and quality of service in rural areas. As a result of a re-examination a revised edition was undertaken and the NDP was passed and adopted in 2004 by implementing significant changes in order to improve the current situation (GNDP, 2004). The objectives of the Ghana NDP are to ensure rational drug availability for all the users including the consumers, dispensers and the prescribers and to enable easy access and equity in health care, and it is this which is proposed could be examined in Kuwait alongside ensuring continuity for the Health System for the future by allowing access to essential drugs by all users irrespective of any financial detriments applied. The Ghanaian National Drug Policy (GNDP) also suggests that it would employ and educate more man power in the health sector which was expected to lead to improvements in quality and quantity of usage of pharmaceuticals at all levels, and it is suggested that State of Kuwait should also take forward this point and develop training programs for Kuwait health professionals to improve their health education and to develop their experiences, to ensure durability of the work in the health services field. On the operational safety side increased training is likely to lead to reductions in medical and administrative errors in the hospitals, health clinics and administrations and therefore increase patient safety. This action is expected to bring into place more efficient drug management by rationalisation of drug procurement and to lead to streamlining supplies and improving drug distribution and other health care delivery systems at all levels,

By studying these examples it is likely to help the senior staff in Kuwait to avoid such issues and problems with reliability in drug procurement through having a well organised system in place centred on establishing an Essential Drug List which could save huge amounts of money and lead to procurement of only the needs of patients and appropriate drugs for the Health Service. Returning to Ghana, in order to have control over public and private sales and the distribution sector, the Ministry of Ghana applied more quality assurance measures for secure and effective drug supplies (Ministry of Health Ghana, 2004).

It is reported that in order to achieve a successful Policy, various strategies were formulated and applied to achieve these objectives such as cost sharing and allocation of examination of resources to areas where people had low access; by enhancing the amount allocated in the drug budget. New procedures were also put into place for improving the drug supply, its procurement and to encourage local production; The Ghanaian Ministry of Health also suggested a flexible approach towards future developments and variations, including keeping the vision for achieving and accommodating the future needs and ensuring a healthy environment for the public of Ghana (Ministry of Health Ghana, 2004).

These are also matters for Kuwait and with the outline of a NPD in place they should be expected to be working towards covering all health aspects and disciplines.

Returning to Ghana, in order to ensure the success of these objectives, the Ghana Authorities have taken certain steps such as providing funding through the Food and Drug Board and the Pharmacy Council and also the formation of a National Pharmacovigilance Centre. The State of Kuwait also suffers from a lack of a Pharmacovigilance Centre and this issue effects generally positively on the health care system where it has been introduced and its absence should be resolved through the establishment of a Kuwaiti NDP.

In the Ghana Public sector, it is the State's procurements methods which prevail, so for effectiveness of procedures an operative procurement unit has been formed in Ghana for health purposes. Ghana's Pharmaceutical Procurement System has become more cost effective by application of an internationally competitive bidding procedure. Through the government's free market policy and through withdrawing the tax exemptions for raw materials used in medicines production it has helped in reducing the local manufacture to a large extent. In addition Health Services have been decentralised and a Revolving Drug Fund Concept has been adopted to improve the drug distribution system.

The Central Medical Stores have also been updated to include increased responsibilities regarding the supply mechanism (Ministry of Health Ghana, 2004).

Added to all these initiatives was the formation of a clinical pharmacy training programme, the introduction of workshops for health professionals and special training for chemical sellers. All these developments have provided the steps to achieve improved Rational Drug usage by guiding the health professionals towards their effective role. In order to provide reliable and unbiased drug information, an Information Resource Centre has been formed both for clients and health providers. However it was found that these developments required improved financial management and adequate drug financing and as a result there was a need to introduce increased economic developments, which included developments in health insurance plans and generic prescribing.

From these developments there is evidence that indicate that healthcare in Ghana is continuing to improve and that the development of the NDP has had considerable influence on this and remains an important area of focus for the Government, with the list of essential medicines continually being updated by the administrating Food and Drugs Authority Ghana (Food and Drugs Authority, 2015).

As with many other African Nations, the major focus of concern for the Ghanaians when drafting the NDP was the prevention of the diseases of HIV/AIDS, tuberculosis and malaria. However the trends in these diseases over recent years has been downwards. For instance TB cases show there to be a continual reduction since the introduction of the NDP, with a concomitant decrease in mortality, suggesting that better prevention and treatment strategies are now in place (WHO, 2015); indeed, it is proposed that treatment success rates are now commonly greater than 80% of the cases identified. Driven on by the success in tackling TB, Ghana has recently increased the budget allocated to eradicate the disease, which now totals $80 million dollars annually (WHO, 2015). Likewise, HIV rates plateaued around the year 2000 due to increased awareness and medical treatments. In this respect it should also be noted that, in providing treatments for HIV victims, there has also been a spread of knowledge through communities where HIV has been widely found and by dealing with the disease there has been a lifting of the stigmas which were associated with the disease. As a result it has

encourages more people to have confidence to visit the doctor and receive treatment.

However, despite these best efforts relating to the development of the NDP, Ghana, like many countries in the developing world, it still has problems in fully delivering effective medication in a cost-effective manner to a large number of people. This is not only due to budget shortcomings but also that there are still concerns over the lack of a fully organized infrastructure, to serve all of the country. As a result it is proposed that education relating to the NDP and a division of labour between the private and public sectors, requires further work. Thankfully, assistance from international organizations, such as the Bill and Melinda Gates Foundation, have provided funding for initiatives which are bringing together private and public institutions in Ghana, with an aim of streamlining the process by which drugs get to patients (Miralles et al., 2003). Efforts in this initiative have included strengthening the drug management systems and procedures by; strengthening the Pharmacy Council's Regulatory Functions; to include improvements in the delivery of medicines to geographically isolated populations; and generating an entrepreneurial spirit amongst local businessmen and women to improve medicines trading, and thus, reduce medicines costs and improve healthcare.

In Ghana one initiatives was the until now the problems of medicines abuses arising after the government introduced exemptions for the low income people at public health institutions and although these abuses have not been completely resolved. The additional establishment of a National Health Insurance Fund (NHIF) in Ghana has helped through drug management and decentralisation of health related services.

As regards the position in Ghana for development of controls in Traditional and Alternate Medicines, a Directorate of the Ghana Health Service has been formed to describe the importance of traditional medicines in the health sector. In this area the Ghanaian efforts have been focussed in providing a platform for all Traditional

Medicine Practitioners under one national organisation. From this they have developed guidelines for standards of practice and ethics, and a training manual for the development of a professional approach in this sector.

With these initiatives there has also been a number of developments in effective monitoring and evaluation, and to assess these initiatives research was conducted through a baseline study of the pharmaceutical sector which has covered issues relating to rational drug use, procurement and financing of drugs. In addition there has been a link to a Group which is involved in the study of Knowledge, Attitudes, Beliefs and Practices (KABP) in Ghana. The NDP has also addressed the intellectual property rights which are covered under Trade Related Aspects of the Intellectual Property Rights agreement (TRIPS). The NDP also provides guidelines for the local manufacture of antiretroviral drugs for HIV/AIDS and their significance in assisting the combating of the disease in the country (Ministry of Health Ghana, 2004).

It is from the experiences of countries such as Ghana that Kuwait can learn many lessons and within this research program the researcher has already started to work on the study of their health status, by finding the main issues and preparing solutions, but in doing so has not neglecting the experiences of other developing countries.

### 2.7.3 National Drug Policy of Namibia

As a further example Namibia has gone through many stages of achieving an operational NDP. The Namibian NDP was established some years ago and initially introduced in August 1998. At that time the foremost objectives were to: meet the pharmaceutical needs of the Namibian public by looking at information on disease identification of health problems specific to the country. This led to a basis of prevention of illnesses wherever possible and to provide effective cures, by

ensuring a supply of good quality medicines for the common diseases at the cheapest possible rates.

Prior to the introduction of the NDP in Ghana, which had been developed along similar lines to other Developing Countries, who had started the NDP route at that time, and had taken information and advice from different agencies of which the WHO was just one, Namibia had put into place several different laws and guidelines to regulate the passage and use of drugs, which formed the basis of their NDP. The most important of these in Namibia was the Medicines and Related Substances Control Act. In order to create a working system the government at the time of introduction of this Act also attempted to integrate a new NDP with this and existing legislation. In addition it also created the Namibia National Pharmaceutical Master Plan which they proposed was designed to meet the aim of delivering overall improved standards of care to Namibians by the year 2000. One of the major aims of these developments (in-keeping with other NDP's developed around the same time) was to develop more fully the major requirements that medicines should be safe, rationally used, efficacious and cost-effective. (Stiftung, 2012)

However in establishing the NDP Namibia, as a relatively poor developing country, had to try to address a great many challenges when it came to acquiring and delivering medicines. These included the relatively low life expectancy in the country which was approximately 64 years of age, which had links to many communities living in relative poverty, in isolation and some distance from major urban centres and therefore not having easy access to medical services. Furthermore, more than 85% of the population was dependent on public health services (Stiftung, 2012), and there was only limited public access to private services. This was despite Namibia having a very large private healthcare sector, one which was similar to South Africa, in which richer individual’s pooled money together in trust funds to help cover their medical expenses. But access was limited to the vast majority of the population which could not afford the private healthcare membership fees. This had created a two-tier system in which the large number of government-dependent individuals had a much-reduced access to health care.

Accordingly, Namibia Health Administrators had to try to deal with the problem of relative isolation from their Health Services of many of its people. Through the organization associated with the development of the NDP they firstly had to find funding to meet the human resource cost associated with access difficulties in the communities. In addition in terms of delivering the access to health services as a priority of the NDP, very few pharmacists were registered in the country (<150), and most were based in the main cities therefore the issue of deliver of medicines, had to be addressed. It was the case that pharmacists from adjacent countries were often the ones serving Namibian residents (Ministry of Health and Social Services, Namibian Government 1998). The Pharmacy Council of Namibia were however at the forefront in the early years of the NDP and they strived to improve the standards and to increase the numbers of properly trained practitioners in the country, although in these early years the actual number of registered members and fully trained pharmacists was unknown.

Added to this position there was also a low number of doctors per head of population at the time of planning and introducing the NDP and at the same time there were financial constraints on the range of medicines which could be purchased. From this information, it was therefore apparent that Namibia faced many pressing issues pertinent to health. Not the least of these was that the Namibian healthcare budget for drugs was only $550 million, and to give a comparison aggregate figure, healthcare costs in the USA totaled $3.0 trillion at that time (CDC, USA 2015). To give another degree of comparison when one considers that most drugs are/were developed and first marketed in the developed countries such as the USA and Europe, where the salaries and funding is generally many times that of the African Countries generally, the economic disparity between the 2 areas made it almost impossible for the developing world to reach very high improvement levels of health. It is therefore the case that unless the global economic model is altered and existing debts erased, countries like Namibia will generally always lag far behind.

It was suggested in establishing the NDP that it would act as a guideline for workforce planning and training, and more effective management of the

pharmaceutical sector, and would bring about legislative reforms in the procurement and handling of medicines. The NDP was also aimed at ensuring a continuous drug supply, with equitable access to all its citizens at affordable prices both in the public and private sectors (Ministry for Health and Social Services, 1998). A review of the Namibia's successful experience in the establishment of the NDP indicates that it would help the State of Kuwait by considering the stated advantages of the benefits of this process and could contribute to the successful introduction of a NDP in Kuwait.

In order to achieve these objectives in Namibia, the Ministry of Health and Social Services increased the regulatory and managerial powers of the Medicines Control Council (MCC). One of the main developments in constructing the NDP was to develop sets of guidelines which provided for the registration of medicines, health practitioners, private hospitals, other health facilities and the enhancement of quality assurance systems. They also introduced registration requirements for generic products which emphasised the importance of GMP and product quality.

Through the NDP the MCC provided a fast track procedure for Essential Drug Registration and computerisation of this process and it was claimed that this computerisation ensured information exchange with regulatory authorities, while maintaining confidentiality. The NDP was also reported to have maintained internationally acceptable standards for medical devices and disposable medical items (Ministry for Health and Social Services, 1998).

As a part of the NDP an Essential Drug List committee was formed for determining the priority drugs required for prevention and cure of prevailing diseases and steps were taken to incorporate the priority drugs into the Namibia Essential Drugs List (Nedlist). This list was designed to ensure that the drugs which were included are based on their international non-proprietary name (INN) or generic name. With the Nedlist in place it was decided it should be reviewed and updated periodically for efficient monitoring. In order to ensure availability of Essential Drugs in the required quantity for the whole population, the NDP imposed limitations on drug procurement of only registered drugs for sole use through Namibian companies, after receiving permission from the Ministry of Health/MCC.

In the NDP the emphasis was also on trying to introduce the rational use of drugs by health professionals as well as educating the population at large by providing strict guidelines for sanction of authority to professionals and dispensers in prescribing and dispensing Essential Medicines. In the NDP there is also a section on introducing the promotion of specialised training and education updates for health professionals and the community. The method of approach was to suggest the development of a systematic and team approach to patient care management, and it was planned to introduce effective control measures to release information which was accurate and to make information available to the public. In addition it was also planned in the NDP to emphasise generic medicines, the rationalisation of the pricing system and its effective monitoring and to negotiate for a cost effective drug supply (Ministry for Health and Social Services, 1998).

It was also the intention of the Namibian Ministry of Health to have a NDP that worked with high standards of control of advertising and promotion of medicines to try to prevent the public from poor quality and counterfeit medicines images by setting National Ethical Criteria for drug promotion. It was agreed that advertisements should be evidenced by scientific proof and they should educate the health professionals (rather than public) as medicines were to be considered sensitive commodities for use mainly by medical prescription. The NDP also provided guidelines for the minimum information recommended about the use of medicines and side effects and the extent of the material presented on the information label/packaging insert.

In Namibia prior to introduction of the NDP, and in the early years of its introduction, the education of the health professionals was introduced to help to bring the NDP into action, and for pharmacists training programs were developed and the staffing requirements were analysed in both the public and private sectors. To assist in this development there was to be an effective association with professional bodies and training involvement through the universities to actively design the pharmacist's curriculum, in tune with the NDP (Ministry for Health and Social Services, 1998). Again these points above and particularly the training are aspects which can be considered in the State of Kuwait.

Another positive aspect of the Namibia NDP which could be introduced once the Kuwait NDP is in place, is the formation of multi-disciplinary research and training of the research professionals to measure the impact of policy and its actions, and this could also be considered in Kuwait.

Added to all of these requirements and guidelines there is also provision for secure and effective use of traditional medicines. This area was also to be strengthened by technical collaboration and harmonisation with other nations. It was suggested that sufficient funds should be allocated to the pharmaceutical sector through the Finance Policy of Namibia for mobilising sustainable National Drug needs.

However overall, the Namibia NDP has appeared to have a beneficial effect in some areas, such as on the number of HIV/AIDs cases in the country. Prior to 2002, the number of HIV-infected individuals was increasing year on year, rising from 2.5% of adults infected in 1992 to 15.8% in 2002. However, since then the frequency has dramatically decreased, something again attributable to increased disease awareness and increased condom usage amongst sexually-active males (Africa Health Observatory, 2017), which was brought about due to increased publicity and health planning. Better management of the condition has also been observed in the country since the implementation of the NDP, although there is still marked room for improvement: 59% of infected females were under anti-retroviral (ART) at public-health facilities in 2011, whereas only 31% of affected males were (Africa Health Observatory, 2017).

Taking the cases of African HIV/AIDs viewed as a whole, it does appear that concerted international efforts to reduce disease burden started around the turn of the millennium and included NDP-directed efforts (by agencies including the WHO) and also efforts by ‘big pharma’ to make their products more available to the developing countries.

Since 2000, Namibia has also seen a remarkable drop in the number of malaria infections and cases, something which is accredited to accessibility and improved use of repellents, anti-malarial medication and increased public awareness through the efforts associated with the NDP. In terms of the actual number of cases in the

country they are reported to have fallen by 99 percent between 2001-2012 (Africa Health Observatory, 2017). However, the impact of global warming on diverse aspects of mosquito and malarial parasite physiology cannot be ruled out as a co-factor in this reduction.

As indicated in earlier sections, one aspect which assists a country in bringing new important medicines to the patients is the speed with which new drugs can be registered, with medicines regulatory bodies. The Namibian health organization have tried out various procedures, as have other countries, in order to try streamline the process of getting new drugs into the clinic. One of the most important criteria for registering a new drug is the checking that the clinical effects of medicines, is carried out thoroughly. Unless this takes place, it is possible that less-efficacious and even dangerous medicines can be allowed through to the patients. In assessing clinical effectiveness clinical trials are the main checking procedure. Carrying out extensive trials in a developing country is however difficult. Where short term trials can be carried out the outcome assessment is also difficult and the best results are not usually obtained without long-term assessments in patient groups to establish safety and efficacy for any medication. An example where this could have been the case was demonstrated by Vioxx, produced by Merck and Co. Ltd., where there were increased deaths due to cardiovascular disease in significant numbers of patients which was not picked up in short-term trials (Krumholz et al., 2007).

There are however many studies which are presently undertaken which can give a better indicator of clinical effectiveness against determining the level of side effect. Future disease incidence trends will be particularly useful for establishing further the efficacy of the Namibian NDP and how it might be improved.

### 2.7.4 National Drug Policy of Kenya

In addition to the experiences of the countries mentioned above, Kenya has provided a number of indicators which were used for the development of their NDP, when it was first established 21 years ago (July 1994). Kenya's NDP was

developed; where one of the main objectives of the Policy was to ensure equitable access to Essential Medicines through the public, faith-based, NGO and private providers.

In setting up of the NDP and it was described as a continuous operation where the Ministry of Health has continued to promote the objectives below:

- Ensure continuous availability of safe and effective medicines in the public sector.
- Ensure that the medicines provided to patients are of good quality, are safe and efficacious both for use in humans and in animals and up to international standards.
- Encourage whenever possible local manufacture of essential medicines and promotion of growth in pharmaceutical exports.
- Promote good prescribing and dispensing and appropriate use.
- Encourage development of traditional, alternative and herbal medicines.
- Continue to provide adequate resources to meet the needs of the pharmaceutical sector.
- Increase and strengthen institutional, technical and human resource capacity for effective pharmaceutical services.
- Promote and regulate pharmaceutical research to make medicines and health technologies more effective, safer and more affordable. (The Kenya National Drug Policy, 1994).

It can be seen by looking at these objectives for Kenya that establishing a NDP in the Developing Countries is of high importance and it is suggested that the Ministry of Health in Kuwait can learn from the experiences of other countries by comparing the starting points and the achievements of the health care system in Kuwait with these countries, and developing and adjusting the NDP by taking into account the appropriate needs and requirements of Kuwait.

If a NDP is to be introduced in Kuwait, it is important that the experiences of countries such as those above are assessed and the important issues considered.

The questions which should be asked are how was the NDP developed for these countries and what have been the benefits for these countries since their implementation?

Firstly, a key aim of the Kenyan NDP was to generate a list of essential medicines (based on the advice of the WHO and others) and to ensure that their procurement received priority. While this practice makes financial sense (and drugs were procured through competitive tender) and ensured that common ailments could be dealt with pharmaceutically (as discussed below), it meant that the Kenyan system faced the same pressures as elsewhere, namely that medicines used to treat less common diseases were seldom available, meaning diverse patient groups still had limited access to pharmaceuticals from the developed world (where it is increasingly a problem); their high cost (associated with research and development expenses and free-market economics) is still a barrier to their acquisition.

However, in Kenya's case they also consider life-expectancy. As an example in the mid-1980s, the life expectancy of Kenyan males reached 60 years of age, although this also coincided with the highest prevalence of HIV in the country; which has been mentioned a number of times in earlier section of the Thesis. It is a notoriously insidious disease which is likely to have been circulating in humans in places such as Kinshasa since the 1920s (Sharp and Hahn, 2011). In the absence of treatment, HIV+ Kenyan patients progressed to AIDs in vast numbers, with the disease being a major contributor to the reduced life expectancy seen by 2000 (Warungo, 2013). However, by 2002 this trend had been reversed, thanks largely to the increasing availability of ART drugs, antibiotics and anti-inflammatory medication. These reached Kenyan patients reasonably efficiently through the organizational structures set up by the MOH. Indeed, ART drugs has recently been scaled-up to meet WHO guidelines for HIV/AIDS; and ART drugs have now been reported as being available to 61% of affected individuals, which is up from 29% in 2007, where it is estimated that up to 214,000 people still had not received any treatment at all (Odhiambo et al., 2014). In light of this it can be suggested that this is one area where the NDP was a success, and it can be suggested that an earlier

implementation may have curtailed major loss of life if available to greater numbers earlier.

As regards the introduction of a NDP and the benefits that can be gained, they are often 'held-up' by financial constraints and organizational agreements to implement which are more-often-than-not the determining factor when it comes to public healthcare systems and their functions – in the developed or developing world. There is overall in countries health development a constant demand for access to new treatments and longevity. However it can be said for countries such as Kenya, the NDP has generally brought with it improvements, such as the National Hospital Insurance Fund and the protections (and health benefits) citizens received from the currents systems in place.

A NDP has also led to improvements with regard to the infrastructure required for the dispensing of medicines; whereas in the past a limited number of individuals (i.e. doctors) dispensed compounds directly to patients, now organizations tend to handle the dispensing, and most are now accredited and designated establishments (pharmacies), giving the public confidence when it comes to acquiring such products. The Pharmacy and Poisons Board of the Kenyan government (Pharmacy and Poisons Board: Registration and Enrollment. Kenya) oversees the training, accreditation and registration for practice in the country, demonstrating further advancement under the NDP.

The Kenyan NDP has had additional benefits with regard to clinical trials and foreign investment. After the NDP was implemented, effectively, a framework for evaluating medicines was put in place. When coupled with increasing hospital infrastructure (including the development of specialist research units and the establishment of good manufacturing practices) and globalization, Kenya began to benefit from large-scale clinical trials being carried out in the country.

One such example is provided by one (of many) trials run by the pharmaceutical company Glaxosmithkline (GSK Ltd., UK) in which an Advanced Market Commitment Scheme was used to fund the development and clinical evaluation of a pneumococcal vaccine, which was later introduced into Kenya’s national

immunization programme in 2011 (Green, 2013). Although MOH have accepted that clinical trials come with risks, they will allow a cohort of patients to be treated (with many patients being treated for the first time), and allow foreign investment (by large pharmaceutical companies) which can generate local jobs and facilities, and help develop academic clinical medicine training in the country. Without a NDP, it is unlikely such advancements would have been possible. GSK recently committed to a £130 million investment in Africa (GSK, 2014), stemming from successes such as the one described.

Furthermore, increasing private investment in medical research – and in particular concerning HIV/AIDS (Gates, Sr., 2003) – through crowd-funding initiatives and non-profit groups (such as MEDS, http://www.meds.or.ke), as well as by large medical research charities like the Wellcome Trust, MRC and Bill and Melinda Gates Foundation, are bringing advanced technologies and therapies to the country. As humans have recently been shown to display geographically- and ethnically-dependent seasonal physiological differences (Dopico et al., 2015; Roederer et al., 2015), such studies not only help us better understand pathology and health in African populations, but also further afield in other countries.

Furthermore, the addition of the passing into law of the provision of veterinary medicine products has been essential for improving the health and wellbeing of Kenyan citizens (Chema and Gathuma, 2004). As a country with a large agricultural population and a long history of animal health (the Kenyan Veterinary Association dates it formation to 1966), many in Kenya live and work in close contact with animals. It is the case that animals that often suffer from the same diseases as humans (such as pneumonia and parasitism), and often transmit diseases to other species, man and between themselves – as we do. Accordingly, it follows that improvements in animal health (through the provision of antibiotics, for example) is associated with improvements in human health; as stated by the currently-popular ‘one health policy’ – stating that improvements in human health benefit animal health, and vice versa (van Helden et al., 2013). Improvements in animal health through education (i.e. how to safely house and care for animals) and the reduction in disease burden leads to reduced zoonosis risk and better food

product yields (indeed, nutrition is strongly associated with health and demonstrates one way in which the NDP has improved the health of Kenyans). The importance of the issue is demonstrated by the fact that the Kenyan government recently formed a Zoonotic Disease Unit (http://zdukenya.org/about-zdu/).

Importantly, the development of the NDP of Kenya has ensured the further exploration of ethnobotanicals, suggesting that they could be further incorporated into modern healthcare policy alongside modern pharmaceuticals. Indeed, further interest in ethnobotanicals in the country has led to wide population surveys concerning medicinal plant use (such as species, route of administration, agreement on effects and side-effects) and the establishment of conservation schemes to protect areas where such rare plants grow (Jeruto et al., 2008).

The NDP of Kenya also stipulates the importance of educational and training programmes to facilitate efficient drug use and to seek out routes to improve academic medicine. Importantly, partnerships between Kenyan and Western institutions are in place – such as the one between University of Nairobi College of Health Sciences and University of Maryland Health Sciences Department (Mayo, 2014) – these help in the transition towards the digital age that is set to become the norm as '*big-data'* is likely to revolutionise biology and medicine in the future (Marx, 2013).

The need for further development of the NDP in Kenya is however been recently shown by the fact that the four biggest causes of death in the country are due to the treatable/manageable diseases of: pneumonia, HIV/AIDs, stroke and diarrheal diseases. It has been proposed however that improved patient access to medication, especially in rural populations and acute situations, will help reduce this burden. As a simple example low-dose aspirin, which benefits the cardiovascular system, has for some time in the western world been recommended for adults at risk of hypertension (from which stroke can arise) (Berger et al., 2008). With better developments within the NDP discussions aspirin as a cheap and easy to manufacture medication could be made more readily available.

2.7.4.1 Some examples of the successes in the policies previously implemented

Kenya has been reasonably successful in 2 notable areas; the introduction of a control program for AIDS where the program is in its fifth year of the health development plan. In addition the Malaria eradication program has lead to a significant drop in the number of cases of malaria. Both of these were developed out of the NDP structure.

Another success in Kenya has been the Expanded Program on Immunization (EPI) which strives to achieve and maintain high immunization coverage and reduction of communicable diseases in children. The immunization coverage had reached 99% at the national level in 2003. Added to this under the organizational structure of the NDP, there has been a notable improvement in the rational use of antibiotics in primary health care which is a goal generally of many developing countries.

With the help of the WHO, the Department of Rational Drug Use in Kenya has conducted a publicity and national survey campaign and recognized inappropriate antibiotic use in the Primary Health Care (PHC) centre. With the operation of a study for only six months there had been a reduction of about 53% in the consumption of antibiotics. The aim of reducing antibiotic consumption was also included into the Kenya National Plan for 2003 with a view to promote the improved rational use of antibiotics (Williams *et al*, 2004).

Relating this to the State of Kuwait, there is generally a large problem of Rational Use of Medicines which is thought primarily to revolve around a high level of self-medication by its people. This can result in irrational (sometimes abuse) of antibiotics, psychotropic, slimming, sexually related drugs and herbal drugs, and it would be proposed that this was one area which should be addressed under the guidelines of pharmaceutical therapy and use in a future NDP for Kuwait. As a result it will be proposed that the KMOH should consider in the NDP, increasing the knowledge of the public by increasing health education programs for the media, in schools and in public areas. In addition they could encourage the establishment of

health education conferences and seminars which support rational use of medicines and describes the health disadvantages of this practice.

### 2.7.5 National Drug Policy of Oman

The examples above relate to African countries and in this section it is proposed to consider how the Gulf Country of Oman has developed and introduced a NDP.

Oman has many similarities to Kuwait in terms of its size, population and pharmaceutical system and its organization. The Sultanate of Oman is situated on the east southern part of the Arabian Peninsula. Oman is classified as the upper-middle income country, similar to Kuwait, according to the World Bank classification. In Oman, the public health sector is well funded and well equipped. 95% of the total population has good access to the public Health Care System. It is also a member of the Gulf Cooperative Counsel (GCC). This includes Oman, Saudi Arabia, United Arab Emirates, Kuwait, Bahrain and Qatar.

Oman published its NDP in the year 2000, and the Sultanate at the time hoped it would better serve the needs of its approximately 4,700,000 million citizens, of which nearly half are under 15 years of age and more than 70% reside in urban centres where infectious disease might spread more quickly than in less densely-populated areas (Ministry of Health, Sultanate of Oman 2000). Life expectancy in Oman is 76 years.

However even before the implementation of the NDP in Oman, the country had been making important progress towards improving the health of its citizens and residents. For example, a total of 24 hospitals in 1975 was surpassed by a total of 47 hospitals in 1999; 80% of which were operated by the Ministry of Health (Ministry of Health, Sultanate of Oman 2000). Therefore, when the NDP came into effect, many infrastructures and the required for its deployment were already in place. In 2000, when data was last collected, there were 302 pharmacies in the country, helping rational dispensing and patient information.

In addition, right up to today the NDP supports the Ministry of Health (the Central Drug Committee) which sets and approves the budget for drugs and determines which medicines appear on the list. Currently, more than 900 drugs and 500 chemicals are on the registry, and all of them have passed rigorous safety, efficacy and manufacturing standards (Ministry of Health, Sultanate of Oman 2000). 200 of these medicines are available only by prescription, representing a large number of entities that can be freely traded. It is proposed however in published literature that improved education on medicines would help more of these compounds to be appropriately used. These include the aspect of drug-repositioning (Sirota et al., 2011) and combination therapies which are becoming more common (Feig et al., 2013).

The general objective of the Oman NDP was to develop the potential that drugs have to control common diseases and reduce suffering. The policy and the government commitment are clearly directed in this way and in establishing the NDP government offices, professional organizations, academia, industry, non-governmental organizations, patients and consumers were all involved in its development (Omani National Drug Policy, 2003).

The policy contains a number of specific objectives which were to:

- Ensure efficient operation of legislation and related regulations, which provide the general public with access to safe, effective, affordable medicines.
- Ensure that medicines imported or manufactured in the Sultanate of Oman are fully evaluated for quality.
- Ensure that there is a selection of drugs and their availability to communities and individuals at an appropriate level that are safe and effective in use.
- Support the procurement system for cost-effective medicines with quality.

- To establish an efficient drug distribution system for constant supply of drugs.

- To provide Pharmaceutical Quality Assurance of any drug product.
- To establish good manufacturing practices, where manufacturing takes place in the country.
- To encourage Good Pharmacy Practice (GPP).

- To improve the use of drugs through rational prescribing and dispensing.
- To ensure the highest degree of co-operation with other Countries and International Organizations to improve the supply, distribution and use of drugs.
- To ensure traditional and herbal medicines are safe and effective.

The NDP of Oman has also benefited from being part of the Gulf States Joint Tender on Medicinal Products (Khoja and Bawazir, 2005), allowing quotations to be evaluated and exchanged between member states, who 'pool' their requirements, which increases the leverage the countries have when it comes to purchasing together commonly expensive products.

### 2.7.6 How can Kuwait benefit from such examples?

Taking together all the points raised in the section above, Kuwait will have many unique challenges to face when it comes to implementing its own NDP. However, there are other countries NDP's which can be used as indicators of the way forward. It has been highlighted in the text above that there are several steps/directions that can be taken to ensure the process runs smoothly and benefits the highest number of people in Kuwait. Steps which could be considered as a means to ensure the smooth running of its implementation and success include:

- Encouraging foreign investment in health care services – this will bring with it not only financial incentives but also experts and businessmen able to share their knowledge with the local economy to establish the best practice. Clinical trials and non-profit research are major ways to achieve this aim.
- Maintaining a continually updated list of essential medicines – in so doing, the most recent evidence concerning safety and indicated/counter-indicated conditions can be taken into account. New medicines should be cautiously added to the list. In the case of Kuwait, it may be advisable to withhold drug registration until efficacy has been established elsewhere (including regulatory approval) or the cost has fallen.
- Joining an international drug-purchasing consortium to secure better prices on drugs and chemical compounds – this can save the public finances several million dollars per year through price negotiations and quotations from different suppliers. If quality can be guaranteed, generic medicines should be purchased to reduce costs.
- Ensuring the infrastructure is in place to allow effective deployment of the new NDP – medicines, without the means to deliver them are not much use. Therefore, an appropriate network of distributors, pharmacists and physicians are required to deliver therapies to patients.
- Perhaps often undervalued, ensuring a high level of medical education reaches the community and patient groups could be amongst the most important steps of any NDP, which should put in place the steps required to inform people that if they need treatment, there are medicines available. In the absence of proper public information dissemination, individuals will not visit the doctor, or if they do, comply with their instructions.
- Kuwait should have a NDP tailored specifically to its unique requirements – What are the diseases present in Kuwait? How can they be treated? How can treatment be delivered? What are the attitudes towards health care in the population?

In short, having reviewed the developments in establishing a NDP in the example countries above and highlighted some of the issues which these countries had to

deal with, these issues and how they have been dealt with will be considered in the establishment of the Kuwaiti NDP. It is proposed that the experiences of these countries are likely to be very helpful in the legislative developments of a NDP for Kuwait to ensure quality, safety and efficacy for the medicines. They can also help in improving the health regulation and legislation, to strengthen the control over medicines usage, to assist in reducing the irrational use of medicines, and improve the drug supply management which can lead to saving in the national budget and to development in the health care system. For these reasons it is suggested that every developing countries should have an interest in the experiences of establishing an NDP for their own country.

Overall in the draft NPD proposed here it may be suggested that the KMOH should re-examine the legislation related to the control of prescribing and dispensing of medicines.

### 2.8 The Health Care System in Kuwait

The State of Kuwait has focused on health since the establishment of the first government after independence in 1961. At that time, the government developed the basis of the healthcare system by establishing hospitals and health centres, providing funding for medical health professionals from abroad and sending its people on medical and pharmaceutical scholarships to countries around the world to gain competencies in the field of medicine, pharmacy and dentistry. In 1976, the Faculty of Medicine (Kuwait University) was established to provide qualified health professionals and to develop their knowledge and skills to improve the health services (Kuwait University, 1998).

The healthcare system in Kuwait has passed through four different stages over the years:

A) Pre-emergence of oil. Kuwait was a very poor country before the discovery of oil, with its economy mainly depending on maritime trade and pearl fishing, and the lack of adequate sources of income negatively affected the standard of healthcare.

It suffered from a lack of hospitals and health clinics in the cities and villages, and Kuwaitis were treated with folk and public medicine. Mortality was common and disease spread rapidly in the country and especially affected children with the spread of epidemics such as plague and smallpox, and also deaths during pregnancy and birth due to poverty, ignorance and lack of necessary health support (Kuwait University, 1998).

B) Establishment of the first British Health Clinic and the American Hospital in Kuwait. With the arrival of the first British political mission in 1904, the High British Envoy advised that the State should bring in physicians to treat the Prince and population of Kuwait, and after that the first health clinic in Kuwait was established by the High British Envoy. Thereafter, in 1910 the American Mission established the American Hospital in Kuwait. This was the first hospital in the State and it started to provide health services and medical treatments. The first gynecologist clinic was established in this hospital which was a major step forward for the health services.

C) Appearance of health care services. In 1949, the first public hospital (Al Ameri Hospital) in Kuwait was established. It consisted of one floor, containing 45 beds. In addition, it had an outpatient clinic, a laboratory and one pharmacy. In the beginning, the health professionals were composed of 13 male physicians and one female physician who specialized in gynecology. It was a major leap forward in the field of health services and the beginning of the organization and establishment of the healthcare system in Kuwait.

D) Health services after independence. In 1961, after independence and the discovery of oil the State had been increasing the infrastructure of the health field by building general and specialized public hospitals and health clinics in all the areas and governorates in Kuwait. Also, the State started to provide and establish medical emergency service centres, a blood bank, central sterilization centre, central medical store and other medical and health facilities. It also began to develop this field in all its technical and technological aspects (Kuwait University, 1998).

By looking at the history of the healthcare system in Kuwait it can be observed that the development of the field has continued with the passage of time. Despite the lack of different sources and difficult conditions in the past, the government has been keen to improve the healthcare system further in order to complete the development of this important area.

Therefore, during the period leading up to this decade, Kuwait has come a long way in developing its health system and has put in place the medical structures and the trained staff to support its health needs. The MOH/Government have to be commended for this. However, as regards the next stage, it is recommended that the organizational structure for delivering the health service would benefit from overviewing the way in which it operates the service and how the health support, in particular the medicines provided to patients, are procured and organized. With this in mind, it is likely that through the establishment of a NDP the service provision and medicines delivery can be enhanced.

This national project on introducing a NDP is therefore considered extremely important in the provision of health support to the population of Kuwait. One major part of achieving this will be the development, improvement and updating of all legislation and regulations which belong to the areas associated with medicines and their delivery in the health sector, where the NDP will provide support to health guideline for health professionals.

Along with other countries with a comparable high human development index and small population (4.2 million in 2016), Kuwait has shown a consistently improving life expectancy over the past century. Currently, the average age at death in Kuwait is nearly 75 years, demonstrative of the good general state of health in the country (World Bank, 2017). Successive Kuwaiti governments have expressed an interest in continually improving the healthcare system and indicated that it has always made it a top concern and priority. Especially after the discovery of oil in Kuwait in 1936, the country's economy has grown sharply and is now has the 4$^{th}$ highest per capita income worldwide. It has to be noted that the health expenditure

per capita in Kuwait is the third highest among the other Gulf States and is considerably higher than the expenditure in developing Africans countries (See Table 2.5). (WHO, 2014)

**Table 2.7 Health expenditure per capita in developing countries (current USD).**

**(Global Health Expenditure Database, 2014)**

| | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|---|---|---|
| Bahrain | 651.47 | 730.12 | 725.75 | 741.57 | 756.55 | 1006.91 | 1142.49 | 1242.84 |
| Ghana | 58.25 | 59.86 | 56.67 | 70.58 | 76.30 | 78.64 | 84.53 | 57.89 |
| Namibia | 293.43 | 285.98 | 332.05 | 405.64 | 486.47 | 467.90 | 470.04 | 499.02 |
| Kenya | 34.99 | 36.60 | 39.29 | 39.41 | 52.99 | 65.06 | 70.00 | 77.70 |
| Oman | 393.60 | 462.07 | 495.79 | 546.64 | 539.86 | 551.58 | 562.89 | 675.043 |
| Qatar | 1563.75 | 1555.81 | 1618.84 | 1483.08 | 1716.89 | 2031.81 | 2067.50 | 2106.35 |
| Kuwait | 963.14 | 1052.24 | 1423.52 | 1041.02 | 1244.29 | 1309.07 | 1252.53 | 1385.78 |
| United Arab Emirates | 1101.01 | 1338.93 | 1332.63 | 1349.45 | 1473.34 | 1433.11 | 1551.35 | 1610.80 |

Over the past recent decades, non-communicable diseases have overtaken infectious diseases as the primary cause of death worldwide, and Kuwait is no exception. Now, the figures show that, the public is more likely to die from obesity, cancer or cardiovascular disease (including cardiac arrest, atherosclerosis, stroke and hypertension) than from a bacterial, protozoal or viral infection (Boutayeb and Boutayeb, 2005). Indeed, in Kuwait, between 1987 and 2000, the biggest causes of death (apart from those associated with hypertension) were ischemic heart disease, traffic accidents and cancers (El-Shazly et al., 2004; Radovanovic, 1994), which demonstrates the point. This change in the threat to health requires a fundamental shift in how we conceptualize and deal with the human condition in Kuwait.

There is also a stark contrast between the ratio of deaths caused by communicable to non-communicable diseases between the Gulf States and the Africans countries. Communicable diseases such as malaria or AIDS are major factors contributing to mortality rates in Ghana, Namibia and Kenya (WHO, 2014). On the other hand, the Gulf States are more affected by non-communicable diseases, such as cancer, cardiovascular diseases and diabetes (considering the prevalence of overweight and obese cases in those richer countries). See Tables below.

**Table 2.8 Diabetes prevalence (% of population ages 20 to 79) in 2015 (International Diabetes Federation Diabetes Atlas, 2015)**

| | |
|---|---|
| Bahrain | 19.6 |
| Ghana | 2.3 |
| Namibia | 4.2 |
| Kenya | 2.4 |
| Oman | 14.8 |
| Qatar | 20 |
| Kuwait | 20 |
| United Arab Emirates | 19.3 |

**Table 2.9 Prevalence of overweight in developing countries (% of adults) (WHO's World Health Statistics, 2014)**

| | **2010** | **2014** |
|---|---|---|
| Bahrain | 69.4 | 71.7 |
| Ghana | 30.3 | 33.6 |
| Kenya | 23.9 | 26.2 |
| Kuwait | 73.3 | 75.4 |
| Namibia | 40 | 42.9 |
| Oman | 64.7 | 67.4 |
| Qatar | 75.1 | 78.1 |
| United Arab Emirates | 72 | 74 |

**Table 2.10 Mortality from Cardiovascular diseases, cancer, diabetes or chronic respiratory diseases between ages 30 and 70 (%) in 2014 (Global Health Observatory Data Repository, 2014)**

| | |
|---|---|
| **Bahrain** | **13** |
| **Ghana** | **20** |
| **Namibia** | **20** |
| **Kenya** | **18** |
| **Oman** | **18** |
| **Qatar** | **14** |
| **Kuwait** | **12** |
| **United Arab Emirates** | **19** |

The increase in non-communicable disease burden could be due to a number of factors. For example, people have suggested that increasing access to modern medicines (especially antibiotics) reduces our life-long exposure to foreign pathogens which over evolutionary time exerted checks and balances on our physiological defence mechanisms (Okada et al., 2010). Some argue that in the absence of such pathogenic challenges, our immune systems have developed abnormally and may even end up attacking our own tissues (as occurs in type 1 diabetes) or altering our metabolism (Liston, 2008).

In addition, it has been proposed that other triggers present in our environment could be pre-disposing us towards developing such diseases; as has been demonstrated by smoking in the case of lung cancer, and a high-fat diet and myocardial infarction (Boutayeb and Boutayeb, 2005) – although the triggers are seldom known. Thus, the role of the environment (and nature versus nurture) should not be overlooked, especially as the increasing burden of such non-communicable diseases is increasing at a quicker rate than could be accounted for by changes in the germ-line DNA sequence; although epigenetic effects have been shown to modulate such phenotypes (Champagne, 2008) and require careful exploration to arrive at disease mechanism – something that would accelerate new

drug development and use. New research should focus on understanding how genetic and environmental factors interact and the consequences on pathophysiology. Along these lines, Kuwait should also, therefore, invest in the research and development of treatments for its own population in order to improve pharmacogenomics and personalized medicine interventions (Chan and Ginsburg, 2011).

Finally, based on the information mentioned above, it could be indicated that all these factors will also need to be taken into consideration before the comparisons and analogies might be drawn between the ways of implementation and development of the NDP in those countries and a possible NDP in the State of Kuwait.

### 2.9 Search strategy

In order to complete this research project, the researcher sourced peer-reviewed, randomized controlled trials and systematic review articles, as well as authoritative reports and book chapters from the following academic text databases:

- PubMed - https://www.ncbi.nlm.nih.gov/pubmed
- Web of Science - http://wok.mimas.ac.uk
- Science Direct - http://www.sciencedirect.com
- Google Scholar - https://scholar.google.com

The keywords used (in search engines) for searches included: National Drug Policy/NDP; NDP in Developing Countries; NDP in Developed Countries; Rational Use of Drugs; Disease Trends; Drug Pricing; Drug Legislation and Regulation; Essential Medicines List; Human Resources Development; Drug Efficacy; Quality Assurance; Drug Counterfeiting; Drug Cost Effectiveness; Pharmacovigilance Center; Drug Registration; NDP Process; NDP Components; NDP Formulation; and NDP Implementation and Development.

Different keywords and databases gave a range of search hits, although commonly many hundreds of records were identified. Across the entire document, 220 publications were found. Of these, 75 have been used by the author as they were relevant to the research study. Further exploration of the references arrived at from the search strategy also allowed for additional references to be found within the text and taken into account. In addition, personal experience and non-English language articles were excluded.

# Chapter 3.0: Research methodology

From the information above, it was proposed that Kuwait should consider developing a NDP as a major step forward in introducing additional improvements in health delivery to its people. The work of this research program is therefore centered around showing more detail of why a NDP is needed and how it should/could be structured and implemented.

## 3.1 Aim

The overall aim of this research program was therefore to establish the basis for the introduction of a NDP for the pharmaceutical sector in Kuwait. This could be achieved by establishing the national priorities and objectives for the pharmaceutical sector and in doing so developing suitable structures, organizations, regulatory guidelines and legislation that could provide the basis to regulate, develop and monitor the health care system.

## 3.2 Objectives

The major objective in introducing a NDP was to establish the basis for promoting the sustainability of the Kuwaiti pharmaceutical sector and to provide

continuous access to reliable, affordable and cost-effective essential medicines. In order to achieve this, it was clear that there was a need for adjustment and extension of pharmaceutical regulations and legislations, and possible changes to certain organizations, and these should be examined in terms of the structure and operation of the pharmaceutical services in the Kuwait. This study intends to do this by:

1. Identifying the main issues and any weakness in the current pharmaceutical healthcare system in Kuwait.

2. Examining the present guidelines for the legislations and regulations which relate to medicines in Kuwait.

3. Establishing the basis for introduction of a NDP.

4. Setting goals and strategies needed for development of a NDP in Kuwait.

### 3.3 Research methodology and examination of the objectives

The research process would involve the following:

- An outline plan of work for the research project.
- The research programme design, which has been discussed with the supervisor(s) and which would lead to the setting up of an appropriate research structure for the project.
- Data collection and methodology across many aspects of the investigation areas which were highlighted as being problematic in the first year studies and the assessment of the current system, which would include in-depth interviews with key personnel; which it was expected initially to take between 2 to 3 months to be completed.

- Organization and presentation of information for Senior Members of the Kuwaiti Ministry of Health (KMOH) to gain approval to continue the programme.
- The methods and data analysis of the current health care system in Kuwait.
- Methods and procedures for the interpretation and utilization of the research.
- Publication of the findings either as an internal document to the KMOH and/or external publication in a suitable journal.

In this research programme, a mixture of primary and secondary data was used. One of the primary data collection methodologies was through the direct interview contact method. For this a number of health care professionals were interviewed face-to-face.

Interview questions were set and formalized; the same set of questions was asked of all respondents. The secondary data collection was mainly through literature reviews and documentary reviews.

## 3.4 Methodology and methods

### 3.4.1 Methodology

Quantitative and qualitative methodologies form the main part of health and social studies. There are many ways to distinguish the quantitative and qualitative approach (Yilmaz, 2013). Quantitative research explains collected data statistically, for example, through self-reported questionnaires. In addition, it involves testing a theory which comprises variables and which are therefore measured with numbers (Gay and Airasian, 2000). The epistemology (the nature of knowledge) of the quantitative approach is based on objectivism (one single reality) and attempts to develop explanatory in health research. It therefore focuses on the measurement of a cause and effect relationship between variables (Denzin and Lincoln, 2005).

As for the qualitative approach, its nature is exploratory and it aims to achieve opinions, beliefs and underlying phenomena (Dingwell and Murphy, 2003). The qualitative method, unlike the quantitative approach, can also involve a small sample size, and participants can be deemed sufficient when they no longer generate new ideas, for example during interview.

A qualitative approach generally uses, why and how questions in contrast to quantitative studies which are generally concerned with how many and how much. A qualitative study often does not depend on one reality but different interpretations. Moreover, it tends to explore the subjective meaning of the participants. Therefore, qualitative research is more able to understand the participants' perspectives and beliefs thoroughly and produce textual data, such as the interviews in the current study (Green and Thorogood, 2004).

To understand participants' beliefs and opinions in this research study and in light of qualitative theory, the author conducted interviews to receive in-depth data. There are however a number of different types of interviews; structured interviews for instance involve predetermined questions which can provide limited answers. Un-structured interviews generate a range of data; these are generally conducted without the author pre-planning the questions (Green and Thorogood, 2004). In the current research, a semi-structured interview procedure was used, which provides a balance between unstructured and structured interviews. This has the benefit of flexibility for the interviewee to elaborate on answers. Moreover, this may support the author to probe and prompt the participants (Green and Thorogood, 2004).

#### 3.4.1.1 The approach used to underpin mixed methods

Mixed methods were used in the current research. The researcher aimed to use both quantitative and qualitative approaches to gain enriched data and to minimize the shortcomings of each approach. It was expected this could enable a deep understanding of collected data being observed. The researcher was of the view that using a questionnaire alone was not enough to generate a broad data base;

and hence this was why the interview method was selected as an appropriate method for collecting data (Creswell and Clark, 2011).

### 3.4.2 Methods

#### 2.4.2.1 Pilot study

Piloting a study is a vital stage in any study as it reduces the limitations of the methods (Bryman, 2004). In fact, it increases the validity, reliability and feasibility of the research instruments (Oppenheim, 1992). All the tools in this study underwent piloting. The questionnaire was piloted on 15 health professionals in order to assist the practicality of the constructed questionnaire, and to receive feedback about the development of the questionnaire and experience about the study. It is important to note that the methods used in the pilot and main stage are similar and are explained as a single set of methods. It is essential to choose a sample population set as it results in valid research. For this reason, the researcher selected an approachable number set that matched the study's aim (Punch, 2013). Therefore, a permission request letter was sent to the Pharmaceutical Associations explaining; the purpose of the study – the development of the NDP in Kuwait – and expressing the researcher's need for health professionals to be involved. This was done by an email which was then forwarded to 200 health professionals out of which however only 121 accepted to take part in the study. The researcher also visited various hospitals, clinics, pharmaceutical administrations and health centers and kindly requested the Administrations to distribute questionnaires to health professionals in order to establish a participation set. (This is discussed in detail in Chapter3, Page 85).

#### 3.4.2.2 Methods of data collection used in the study

1. **Questionnaire: Establishing a National Drug Policy in Kuwait**

The researcher used questionnaires (See Appendix 1) as one of the vital data collection tools for the study. The questionnaire was expected to help to elicit

various experiences and opinions regarding the operation of health care professionals in different areas of the health care system in Kuwait, relating to Pharmaceutical Services, which served to add credibility to the findings. The items listed in the questionnaire of this study were constructed by talking note of four other questionnaires in the literature, as they were the most relevant to the objective of this research. For instance five questions (Q4, Q7, Q9, Q11 and Q12) in the constructed study questionnaire were adapted by considering the work of Phnouvong (2008) who conducted a study in the USA specifically relating to medicine quality assurance and medicine quality control activities in a pharmaceutical supply system. These adapted questions were selected for the researcher's questionnaire due to their relevance in terms of drug control and monitoring, EDL, access to quality, aspects of drug safety and efficacy, and the establishment of a NDP. However, other items in Phnouvong's questionnaire were excluded as they covered specific aspects such as product packaging and labeling, product delivery and transportation, defective product recall and handling, and rejected products.

The designed questionnaire for this study also took note of five other items (Q1, Q2, Q5, Q6 and Q8) which were from the Jaffar, S. and WHO (2011) who undertook a study based in Oman which examined the strengths and weaknesses of their pharmaceutical situations relating to the health services, drug policies and regulations, rational use of drugs, selection of drugs and drug pricing. The questions from the WHO study were noted because they discussed aspects of the implementation of a NDP, human resources development, drug pricing policy issues and the irrational use of drugs. All these areas are related to the focus of this research. Other areas of these studies mentioned which assisted the development of the questionnaire which were because they did not support the objectives of the research included types of disease, neonatal mortality rate, the prescribing policies and clinical trials.

Furthermore, one question (Q10) from the designed questionnaire for this study was considered from the study of Wondemagegneha (1999) whose questionnaire presented a basis for studies conducted in Myanmar and Vietnam concerning the

assessment of counterfeit drugs and its effect on the health care system. Therefore, Question 10 in this study's questionnaire focused on the importance of the existence of the pharmaceutical supply chain in the country and its effect on the access to medicines for the health care system in both the public and private sectors. Again, the rest of the questions in Wondemagegneha's questionnaire were not considered closely relevant as they did not support the aim of the research such as drug imports and drug outlets.

Finally, Question 3 in the constructed questionnaire was examined and adapted from Elmi (2013), who carried out a study in developing countries of East Africa as well as the Middle East. Elmi's questionnaire discussed information in regards to the access, safety and quality of drugs in these emerging areas and how to increase control and evaluation over counterfeit drugs. Thus, Question 3 was designed to study the aspect of issues concerned with the organization of the pharmaceutical side of the health care system. In that respect careful consideration of the relevance of others work was carried out and irrelevant topics about places where patients purchase their medicines, questions about patient's visits and discussions that take place between patients and physicians were excluded.

### 2. Interview to assess opinions of health care professionals

Interviews are considered a valuable means of gathering in-depth data on a large range of topics (Dornyei, 2007). However, Grimm (2010) claims there is a common concern that arises during interviews, which is the participants' desire to reflect themselves in a progressive way, by giving controlled satisfactory answers rather than expressing their honest opinions. However, Cohen et al. (2007) states that such an issue should not prevent a researcher from conducting an interview if care is taken, as the feedback from it can be contrasted with responses from other collected data. For this reason, this study carried out here as part of this research has focused on more than one type of data collection. This section of the study was conducted using a semi-structured approach. It was chosen because it enabled flexibility for the interviewee in terms of the planning of the structured

questions in advance while also allowing other relevant questions to be raised, if it was considered necessary in order to reach the study's objective (Pawar, 2004). Therefore 12 questions were constructed and the same questions were asked of all respondents who were taking part (See Appendix 1).

It was also considered very important for the researcher to make various efforts not to impose their opinions on the participants during discussions. Overall the purpose of the interview was to explore participants' understanding of the health care system in Kuwait and whether any suggested solutions were found towards enhancing it. It is important to note that the researcher conducted interviews with participants individually to make them feel comfortable in giving honest answers (Creswell, 2009).

## 3.5 Validity and Reliability

**Establishment of a NDP in Kuwait**

### 3.5.1 Validity

The extent of the success which a researcher has in assessing what they planned to measure is considered as validity. External validity is the ability of the study to be generalized to other situations and to other people (Bowling, 2014).

However, in the current study the focus is on the qualitative approach because the researcher intended to understand the experience and perspectives of the participants. As such, however the findings in this study are hard to generalize. The type of analysis of this data include: Internal Consistency Validity (Validity was discussed in details in Chapter3, Page 84).

### 3.5.2 Reliability

Reliability is the level to which procedures are consistent when performed by different participants. In this case the author used the questionnaire to assess the objectives output of the participants (Murphy and Dingwall, 2003).

The questionnaire therefore was intended to evaluate the direct experience of health care professionals in regard to the development of the health care system in Kuwait. In terms of the operating system used the questionnaire was sent to the participants before meeting with them. The reason for this was the expectance that; this was more likely to make participants more comfortable with the questionnaire and familiar with the type of questions.

For the meetings, to enhance the reliability, the author gave participants the opportunity to choose the meeting place and time which was suitable to them. In effect, all of the participants agreed to an interview with the author at their place of work (Murphy and Dingwall, 2003).

The researcher planned to ask the participants the same questions in the same style to enhance the consistency of their responses. However, it was accepted that their experience in the health care system might vary. Moreover, the researcher did not guide the participants towards a certain agenda but rather tried to understand their opinions and recommendations, which again was considered might enhance the reliability of data.

In addition, it can be said that an interview belongs to the interpretivist paradigm, and in order to achieve this the author used audio recording to capture the subjective meaning of the participants (O'Leary, 2004).

Semi-structured Interview

There are many types of interview for the purposes of collecting data; one of these methods is the semi-structured interview. This type of interview facilitates the participants to talk freely and encourages the researcher to understand the opinions and concerns of the participants. It is considered that this style of communication with the participants is more likely to make them comfortable (Ritchie et al., 2003).

Audio recording

Legard et al. (2003) also mentioned that the participants should agree that their interview with the author is recorded before they take part in the study.

Furthermore, using audio recording increases the reliability of data collection in detailed (Ritchie et al., 2003). However, some of the participants in the study indicated that they preferred that the interview was not recorded. Thus, the author documented the participants' account and then sent this to those participants to enhance the reliability of the interview. The recorded interviews were transcribed verbatim (Murphy and Dingwall, 2003).

In addition, in order to enhance the reliability of data the transcripts were uploaded to SPSS 10 software (QSR, 2014) in order to facilitate management of data. SPSS helps the author to code and in the retrieval function (Pope, 2006). The type of analysis of this data includes the Split Half Method and Spearman and Brown Correlation Coefficient (Reliability was discussed in details in Chapter 3, Page 89).

### 3.5.3 Quantitative approach

A positivist view (dependent on factual knowledge) assumes that the behavior of people can be quantified. Therefore, as Smallbone and Quinton (2004) suggests, the tool for the measurement of human behavior should be reliable and valid.

### 3.5.4 Qualitative approach

In the current study, an in-depth interview was used to understand the participants' experiences of the health care system in Kuwait.

## 3.6 Sampling

A code of ethics normally guides an author who plans to conduct interviews with participants. In this case the sample of those interviewed also included the Assistant Undersecretary of Drugs and Medical Supplies Affairs in the KMOH, pharmacists, physicians, nurses, senior academics at Kuwait University and the Kuwaiti Pharmaceutical Association. In the current study, the sample was a non-

randomized but a purposive one which it was hoped would support the author to generate data for the research study (Holloway and Wheeler, 2010).

The total participants who were invited to take part in this study were 200 different health care professionals. Of these, 120 invitations were sent to pharmacists, 50 to physicians and 30 to nurses.

The respondents were health care professionals with varying levels of experience of the structure, regulation and organization of pharmaceutical work in Kuwait; generally they possessed a good degree of knowledge in their field. They were also selected from each division of the KMOH. As a basis for this, advice was taken for the WHO, for such a study, where they suggested that the inclusion criteria should focus on members who are responsible for the efficiency of the health care system. As a result, inexperienced health care professionals in low level positions in the health care sectors were excluded from the questionnaires and interviews. In addition, a number of health care professionals from the private sector were included in the study.

### 3.7 Ethical considerations

The requirements set out in the code of ethics were noted before the study was conducted to ensure the confidentiality and safety of all participants (See Appendix 2). It is considered to be the responsibility of the researcher to reduce the harm which may result from the engagement of the participants in the study, particularly participants' personal information. Another responsibility of the researcher involves the participants being made aware and freely deciding whether to take part in the study (Murphy and Dingwall, 2003). In other words, consent was sought in order to reduce the harm to participants.

Ethical approval was issued and approved by KMOH (See Appendix 2 ) on the basis of the heading of – 'Development of a National Drug Policy in Kuwait', by a concerted interview with concerned health professionals and data would be

collected relating to drug regulations and legislations of the health care system in the country.

In the piloting stage and second phase, the participants would receive a consent form and an information letter to inform them about the nature of the study (Appendix 1 - Consent Form). In the main method (second phase), ethical approval was required and the KMOH was responsible for that.

In addition, ethical approval was obtained through the Kuwait Ethical Panel, for which a supporting letter from the University of Bradford (where approval was also achieved) was sufficient to allow clearance for data collection. It was made clear that the data gathered was not of human health origin and no patient information was gathered.

As indicated above, written consent was obtained from all respondents after thorough explanation of the purpose and nature of the study. Anonymity, confidentiality and safety in the handling of the data gathered were explained. Each respondent was asked to date and sign the consent form if they were willing to take part in the study.

### 3.8 Recruitment

The recruitment of the participants in this study was undertaken over two phases: the piloting phase and the second phase. The former was made up of a sample size of 15 participants (pharmacists, physicians and a nurse). Ten pharmacists worked at KMOH; four worked in public health administrations (CMS, DCA, DIA, PSA), four worked in public hospitals; and two worked in public health clinics. Of the four physicians, two worked in public hospitals and two worked in public health clinics. The nurse worked in a public hospital. All participants were invited via email as the main aim was to collect initial data in order to conduct the main method of this study. The latter (the second phase) focused on achieving the objectives of the study by increasing the number of participants (121 health professionals).

The researcher visited a number of health locations (KMOH, Dasman Diabetes Institute, public and private hospitals, health clinics and pharmaceutical companies, and the School of Pharmacy) and explained the current study to the directors in order to seek assistance. Of 200 emails sent, 121 recipients expressed an interest in participating in the study. The researcher was satisfied with a sample size above 100 as it was adequate to reduce the margin of error to a reasonable level (Grasley, 2007). Participants were interviewed in a place and time of their choosing. Data collection was completed within six months due to the restrictions of time and availability of participants.

The places where the collection of information from Kuwait was made are shown below:

A. Kuwaiti Ministry of Health

The current structure of the pharmaceutical sector under the KMOH is divided into 4 main administrations and includes:

1. Pharmaceutical Services Administration (2 pharmacists interviewed).
2. Drug Inspection Administration (2 pharmacists interviewed).
3. Drug and Food Control Administration (8 pharmacists interviewed).
4. Central Medical Store Administration (5 pharmacists interviewed).

The four Administration Units are managed through the Assistant Undersecretary of Drugs and Medical Supplies Affairs in the KMOH. Each of the administrations has its own general director and administrative structure, and is responsible for regulating and developing its own work and seeking to ensure appropriate services to consumers and improvements in the health care system under the supervision of the KMOH.

B. DASMAN Diabetes Institute

This Institute is the only Research Centre in Kuwait. During a visit to it, the Assistant Director of the Centre and the Head of the Diabetic Department were

interviewed. Data was also collected about how the Institute undertakes its responsibilities and operating system.

C. Public and private hospitals, health clinics and pharmaceutical companies in Kuwait

Data collected from the public and private sector is included in this work, namely interviews with health professionals (79 participants) and investigations to identify the nature of the work and knowledge of the most important requirements and issues in these places.

D. Drug Release Department at Kuwait Airport

This Department is responsible for release and control of all medicines, pharmaceutical products and medical devices received into Kuwait International Airport in cooperation with the Drug and Food Control Administration.

The data collected from this Department included an interview with the Head of Department and data relating to the way the Department works, the staff and staffing, and any issues and requirements.

E. School of Pharmacy at Kuwait University

Data was collected from the School of Pharmacy of Kuwait University and included interviews with the Vice Dean of the School of Pharmacy and the Head of Quality Assurance Department of the School of Pharmacy.

There were also some discussions with academic staff on the importance of a NDP and suggestions on how to solve the issues of the health care system in Kuwait.

[Note It should be noted that the Assistant Undersecretary of Drugs and Medical Supply Affairs at KMOH, Dr. Omar AL Sayed Omar, is acting as an external supervisor on this research program and indicated at an early stage that he would provide support for data gathering and advice until the PhD thesis was completed (See Appendix 2).

## 3.9 Analysis of results

### 3.9.1 Quantitative results

This study therefore made use of one questionnaire to assess the experiences and suggestions of the participants in regards to improving the health care system and specifically the pharmaceutical field by identifying the main issues and weaknesses of the current health system, understanding the nature of work in the public and private sectors, finding solutions and setting out a future plan of action.

As indicated above, in terms of assessing the results, the questionnaires were recorded manually by the researcher and then the data were uploaded to version 10 of SPSS. SPSS is one of the most popular statistical programs. It allows for the construction of complex graphs and illustrations from statistical data. Both forms will be used in this PhD project report (Taylor, et al., 2003). In addition, SPSS will assist in converting the qualitative data to quantitative data and analyzing the qualitative data from the interviews with the health professionals in Kuwait (Woods, 2011).

In terms of the method of primary data collection (questionnaire and interview) is the observation method. This involves the gathering of primary data by the investigator's own direct observation of relevant people, actions and situations without directly asking questions of the respondents. The type of analysis of these data include: Descriptive Analysis, Chai Square Test ($x^2$), One Way Analysis of Variance, T-Test and Shefe Method (were discussed in details in Chapter3).

In this study, 11 questions were constructed, which were asked of all respondents who were taking part (See Appendix 1).

The questionnaire used 2 types of scales:

1. Questions 1, 3, 6, 8 and 9 were scored using a five Likert scale: 1 = very important, 2 = important, 3 = not applicable, 4 = not important, and 5 = useless.
2. Questions 2, 4, 5, 7, 10 and 11 were scored using a Yes/No style system: 1 = yes and 2 = no.

In addition, the chosen questions of the questionnaire were determined based on the structure and basis of a NDP. All appropriate health aspects were included: monitoring and evaluation, human resources development, economic strategies for drugs, rational use of drugs, quality assurance, supply management, selections of drugs (EDL), and legislations and regulations of drugs (adapted from WHO, 2001).

### 3.9.2 Qualitative results

The nature of a qualitative study elicits participants' experiences in an asocial context which is not standardizing (Murphy and Dingwall, 2003).

The presence of the author may also affect the collected data. However, as stated earlier, no personal information or questions were taken from the participants, which made it more likely for the participants to be open with the author. In addition, the recruited participants were professionals and so potentially there was no power imbalance which would have been the case had the participants been patients (O'Leary, 2004).

The overall conclusion from this chapter is that a lack of previous studies and data on the subject of a NDP in Kuwait forced the researcher to use relevant previous studies to build the questionnaire.

# Chapter 4.0: Analysis of Interview Data

## 4.1 Introduction

As discussed in the previous chapter, the researcher built the questionnaire after reviewing the theoretical literature and previous studies related to the subject of current research in order to verify the psychometric properties (Validity and reliability) of the questionnaire on Establishing of a National Drug Policy in Kuwait. The questionnaire included 12 questions:

1. How important is having a national drug policy (NDP)?
2. Do you think we can develop and improve the health care system in Kuwait?
3. Are there any issues of concern with the organization of the health care system in Kuwait?
4. In the public and private sectors, do you think we have enough control over regulating the process associated with pharmaceuticals?
5. Do you feel that the training of health professionals in the public and private sectors is sufficient?
6. Do you think that the price range of medication in the private sector is publically acceptable?
7. Do you think that there are any issues with access to quality, safe and efficacious drugs?
8. Do you think that there is an irrational use of drugs in Kuwait?
9. How important is having an Essential Drug List?
10. Do you think that Kuwait should develop its own pharmaceutical industry?
11. Do you think it is time to establish a NDP in Kuwait?

The questions were divided into two, with the first part containing 11 questions. The second part involved a sub-question (Appendix 1). The target of these questions was to direct a specific question to the research sample as shown in the previous questions above. The structure of the questionnaire was as follows:

- Questions 1 and 9 contained five responses and were arranged according to the following scale: Very important – Important – Not applicable – Not important – Useless, and each response was given scores to be analyzed by using SPSS, as the following: Very important with 5 scores, Important with 4 scores, Not applicable with 3 scores, Not important with 2 scores and Useless with 1 score.
- Questions 3, 6 and 8 contained five responses and were arranged on the following scale: Strongly agree – Agree – Not applicable – Disagree – Strongly disagree, and each response was given scores as the following: Strongly agree given 5 scores, Agree given 4 scores, Not applicable given 3 scores, Disagree given 2 scores and Strongly disagree given 1 score.
- Questions (2, 4, 5, 7, 10, and 11), contained two responses and arranged as (Yes – No), and each response was given scores as the following: Yes given 2 scores and No given 1 score. Table 4.1 shows description of the questions from the first part of the questionnaire, its responses and scores.

**Table 4.1 Questions from the first part of the questionnaire, its responses and scores.**

| Question No | Responses | Scores | Max Score | Min Score |
|---|---|---|---|---|
| 1 and 9 | Very important – Important - Not applicable - Not important - Useless | From 5 to 1 | 5 | 1 |
| 2, 4, 5, 7, 10 and 11 | Yes – No | From 2 to 1 | 2 | 1 |
| 3, 6 and 8 | Strongly agree – Agree – Not applicable – Disagree – Strongly disagree | From 5 to 1 | 5 | 1 |
| Total | | | 37 | 11 |

While the second part of the questionnaire involved 12 interpretive questions, and each question from the second part was focused on directing an interpretive question to the research sample following each question of part one as mentioned in Table 4.2. In addition, it was observed that the responses of research samples differed from one question to another in the second part (interview), as mentioned in Table 4.3.

**Table 4.2 The number of questions from the second part of the questionnaire**

| No. of Question | Question |
|---|---|
| 1, 3, 5, 6 and 11 | Please explain? |
| 2, 7, 8 and 9 | How? |
| 4 | If No, please explain? |
| 10 | Explain how can we develop? |
| 12 | If yes, do you think it will influence the health care system in Kuwait? |

**Table 4.3 Responses to questions from the second part (interview) of the questionnaire**

| Question No | Responses | No of Responses |
|---|---|---|
| 1 | A-B-C-D-E | 5 |
| 2 | A-B-C-D-E | 5 |
| 3 | A-B-C-D-E-F-G-H | 8 |
| 4 | A-B-C-D-E-F | 6 |
| 5 | A-B-C-D | 4 |
| 6 | A-B-C-D | 4 |
| 7 | A-B-C-D | 4 |
| 8 | A-B-C-D-E | 5 |
| 9 | A-B-C-D-E | 5 |
| 10 | A-B-C-D-E | 5 |
| 11 | A-B-C | 3 |
| 12 | A-B-C-D-E | 5 |

### 4.2 Validity of Questionnaire

Validity is a research method that is used to describe whether the results obtained from the study meet all of the requirements of scientific research method and whether the research study measures what intends to measure (Csikszentmihalyi, et al., 2014). Two main type of validity are available: internal and external validity (Bolarinwa, 2015). Internal validity refers to the validity of the measurement and test itself, whereas external validity refers to the ability to generalise findings to the target population (Bolarinwa, 2015).

The researcher has resorted two types of validity checking: Specialists Validity and Internal Consistency Validity.

### 4.2.1 Specialists Validity

After preparation of the questionnaire, it was presented to a group of faculty members in the Kuwait Pharmaceutical Faculty (Vice Dean of Pharmaceutical Faculty and Head of Pharmaceutical Department of the Faculty) and was also presented to Assistant Under Secretary for Drug and Medical Supplies of KMOH. Then, the researcher asked them to modify the questions that need to be amended in the area of the procedural definition of what is measured by the questionnaire; to edit responses that were in need of amendment; and to judge the appropriateness of the questions when measured by the concept. This resulted in analysis by the researcher of the modifications of these arbitrators in order to arrive at the strongest possible version.

### 4.2.2 Internal Consistency Validity

This refers to a measure of consistency based upon the amount of correlation between different data points within the same dataset (Bentler, 2009). In other words, it monitors whether two (or more) different data points which might be expected to have similar values really do have similar values.

Initially the questionnaire was conducted on a pilot sample of health professionals working in Kuwait, which amounted to a sample size of 15 participants (pharmacists, physicians and a nurse). The correlation coefficient between pilot sample scores on each question and the total score for the two parts of the questionnaire (parts 1 and 2) was calculated. The same calculation was done for each part separately (the results are given in the following tables).

**Table 4.4 Correlation coefficient between the pilot sample scores on each question from the first part of the questionnaire and the total score**

| Question No. | Correlation Coefficient (R) |
|---|---|
| 1 | 0.280 ** |
| 2 | 0.286 ** |
| 3 | 0.279 ** |
| 4 | 0.366 * |
| 5 | 0.291 ** |
| 6 | 0.370 * |
| 7 | 0.412 * |
| 8 | 0.561 * |
| 9 | 0.282 ** |
| 10 | 0.571 * |
| 11 | 0.511 * |

* R (48, 0.01)=0.354 ** R (48, 0.05)=0.273

This table shows that all the questions from the first part of the questionnaire were correlated with the total score of this part and the correlated significance was at the level of (0, 05) and (0, 01). This result indicates that the questions in the first part were closely correlated to the questionnaire.

**Table 4.5 Correlation coefficient between the pilot sample scores on each question from the second part of the questionnaire and the total score**

| Question No | Correlation Coefficient (R) |
|---|---|
| 1 | 0.467 * |
| 2 | 0.523 * |
| 3 | 0.290 ** |
| 4 | 0.486 * |
| 5 | 0.572 * |
| 6 | 0.291 ** |
| 7 | 0.290 ** |
| 8 | 0.527 * |
| 9 | 0.462 * |
| 10 | 0.581 * |
| 11 | 0.279 ** |
| 12 | 0.529 * |

* R (48, 0.01)=0.354 ** R (48, 0.05)=0.273

This table shows that all the questions from the second part of the questionnaire were correlated with the total score of this part and the correlated significance was at the level of (0, 05) and (0, 01). This result indicates that the questions in the second part were closely correlated to the questionnaire.

**Table 4.6 Correlation coefficient between the pilot sample scores of the questions from the first part of the questionnaire.**

| Ques No | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ——— | | | | | | | | | | |
| 2 | 0.361 | ——— | | | | | | | | | |
| 3 | 0.422 | 0.321 | ——— | | | | | | | | |
| 4 | 0.567 | 0.566 | 0.496 | ——— | | | | | | | |
| 5 | 0.511 | 0.511 | 0.522 | 0.467 | ——— | | | | | | |
| 6 | 0.481 | 0.311 | 0.297 | 0.521 | 0.411 | ——— | | | | | |
| 7 | 0.281 | 0.290 | 0.316 | 0.531 | 0.528 | 0.416 | ——— | | | | |
| 8 | 0.311 | 0.571 | 0.481 | 0.518 | 0.469 | 0.592 | 0.413 | ——— | | | |
| 9 | 0.322 | 0.486 | 0.567 | 0.281 | 0.327 | 0.517 | 0.528 | 0.582 | ——— | | |
| 10 | 0.561 | 0.523 | 0.528 | 0.469 | 0.288 | 0.316 | 0.565 | 0.513 | 0.568 | ——— | |
| 11 | 0.527 | 0.416 | 0.316 | 0.590 | 0.519 | 0.528 | 0.534 | 0.586 | 0.481 | 0.312 | ——— |

* R (48, 0.01)=0.354 ** R (48, 0.05)=0.273

This table shows that the questions from the first part of the questionnaire were correlated with each other and the correlated significance was at the level of (0, 05) and (0, 01). This result indicates that the questions in the first part were closely correlated to each other.

**Table 4.7 Correlation coefficient between the pilot sample scores of the questions from the second part of the questionnaire.**

| Qu No | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | —— | | | | | | | | | | | |
| 2 | 0.281 | —— | | | | | | | | | | |
| 3 | 0.421 | 0.526 | —— | | | | | | | | | |
| 4 | 0.568 | 0.257 | 0.489 | —— | | | | | | | | |
| 5 | 0.289 | 0.569 | 0.522 | 0.531 | —— | | | | | | | |
| 6 | 0.567 | 0.291 | 0.567 | 0.491 | 0.563 | —— | | | | | | |
| 7 | 0.468 | 0.281 | 0.433 | 0.312 | 0.491 | 0.519 | —— | | | | | |
| 8 | 0.429 | 0.543 | 0.292 | 0.511 | 0.487 | 0.428 | 0.531 | —— | | | | |
| 9 | 0.529 | 0.492 | 0.481 | 0.528 | 0.293 | 0.310 | 0.419 | 0.566 | —— | | | |
| 10 | 0.279 | 0.561 | 0.295 | 0.417 | 0.317 | 0.291 | 0.317 | 0.492 | 0.511 | —— | | |
| 11 | 0.281 | 0.416 | 0.311 | 0.280 | 0.461 | 0.561 | 0.322 | 0.317 | 0.312 | 0.521 | —— | |
| 12 | 0.551 | 0.290 | 0.428 | 0.276 | 0.515 | 0.572 | 0.519 | 0.489 | 0.370 | 0.436 | 0.312 | – |

* R (48, 0.01)=0.354 ** R (48, 0.05)=0.273

This table shows that the questions from the second part of the questionnaire were correlated with each other and the correlated significance was at the level of (0, 05) and (0, 01). This result indicates that the questions in the second part were closely correlated to each other.

The overall conclusion from this section of the study is that the information presented above indicates that the validity of questionnaire was closely acceptable.

### 4.3 Reliability of Questionnaire

In addition to the above, to increase the reliability of the questionnaire, a split-half method was used. The questionnaire was piloted with 15 participants (pharmacists, physicians and a nurse) in the pharmaceutical sector. A correlation coefficient was calculated between the pilot sample scores of the questions in the first part of the questionnaire, which revealed a consistency of (0.480). Therefore, to strengthen the reliability and credibility of the score, the Spearman-Brown formula (This non-parametric measure of correlation assesses how well a relationship between two points can be described using a monotonic function, and is a rank correlation method) (Sedgwick, 2014) was applied which indicated a correlation number of (0.649), which is significant at level (0.01). Moreover, a calculation of the correlation coefficient between pilot sample scores of the second part of the questionnaire (interview) was also conducted, and showed a significance of (0.461). Hence, (0.631) at level (0.01) in the Spearman-Brown formula, which indicates a high level of reliability. The questionnaire therefore fulfills psychometric characteristics, which makes it possible to be used with the research pilot sample.

## 4.4 The interview procedure and examination of the data generated by the interviews of senior staff

121 health professionals were interviewed from both the public and private sector in Kuwait in the period February 2012 to June 2013. As indicated in the earlier section these professionals included pharmacists, physicians and nurses.

4.4.1 Interviews in public sector

- The interviews in the public sector were carried out in 19 health locations distributed across public health administrations, public general hospitals, public specialized hospitals, public health clinics, Dasman Diabetic Institute, public military hospital, Public National Guards Clinic and the University Pharmaceutical Faculty. The interviews were conducted with 101 health professionals from the following institutions:

1. Kuwait Food and Drug Control Administration, (8 pharmacists).
2. Kuwaiti Central Medical Store Administration, (5 pharmacists).
3. Kuwaiti Pharmaceutical Services Administration, (2 pharmacists).
4. Kuwaiti Drug Inspection Administration, (2 pharmacists).
5. Mubarak Hospital (General Hospital), (7 physicians).
6. Al Amiri Hospital (General Hospital), (3 pharmacists and 2 nurses).
7. AL Sabah Hospital (General Hospital), (14 pharmacists,1 physician and 3 nurses).
8. Qortoba Clinic (Public Health Clinic), (10 physicians).
9. Shaikhan Al Farisi Hospital (Endocrine Hospital), (3 pharmacists and 3 physicians).
10. NBK Hospital (Pediatric Hospital), (4 pharmacists).
11. Medicine Hospital (Internal Hospital), (8 pharmacists and 4 physicians).
12. Ibin Sina Hospital (Neurological Hospital), (6 pharmacists).
13. Al Bahar HospitalL (Ophthalmology Hospital), (1 pharmacist and 1 physician).
14. Dasman Diabetic Institute (Diabetic Research Center), (2 physicians).

15. Hamed AL Essa Hospital (Renal and Organism Transplantation Hospital), (2 pharmacists).
16. Military Hospital (General Hospital), (2 pharmacists).
17. National Guards Clinic (Health Clinic), (1 pharmacist).
18. Pharmaceutical Faculty (Kuwait University), (2 pharmacists).
19. Assad Al Hamad Hospital (Dermatology Hospital), (4 pharmacists).

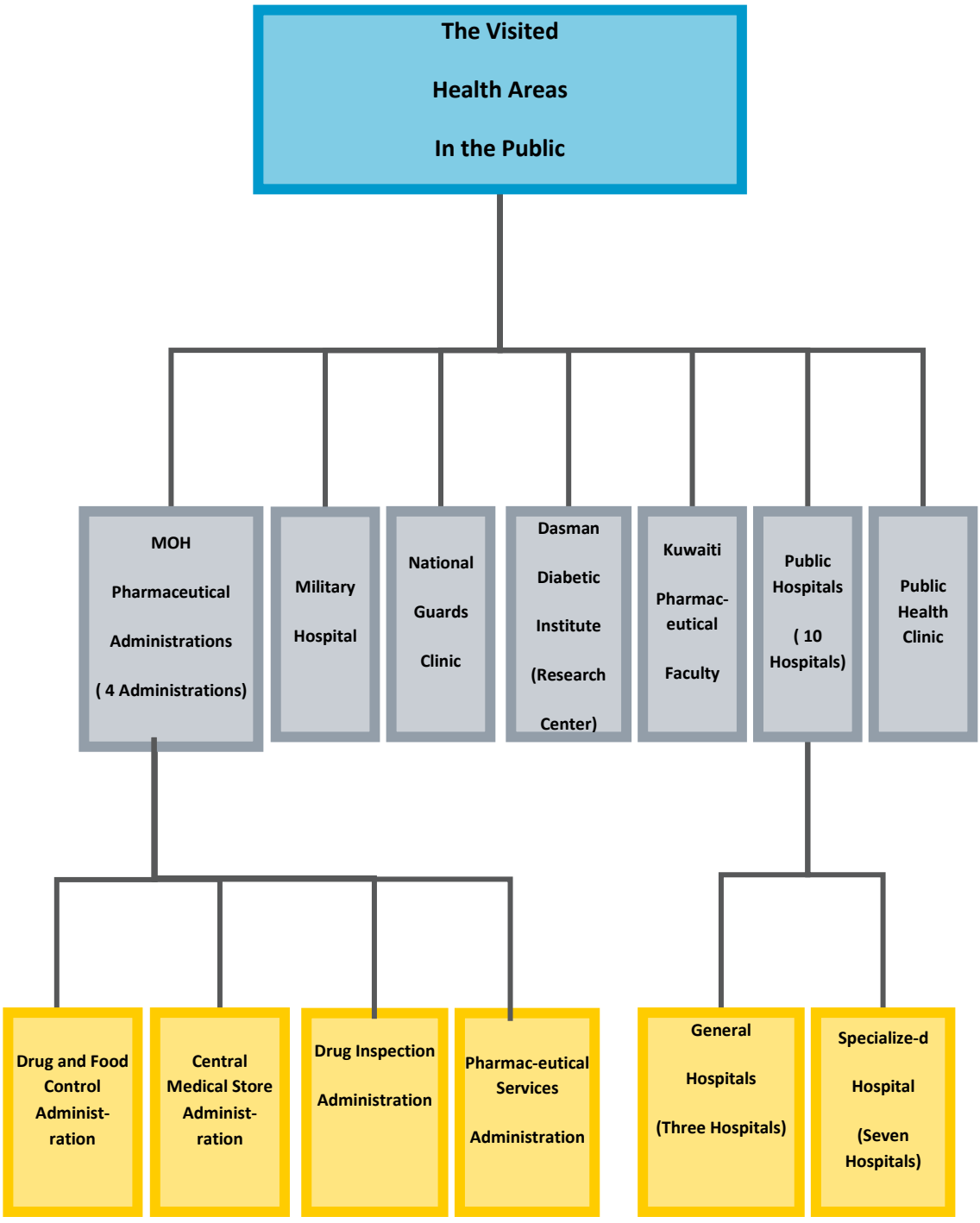


**Figure 4.1 The Public Health Areas visited during the Interviews**

- In addition to the health professionals, a number of very senior staff working in different places in the public health sector was interviewed as listed below:

1. Assistant Under Secretary for Drug and Medical Supplies of KMOH.
2. Director of Drug Inspection Administration.
3. Director of Drug and Food Control Administration.
4. Director of Central Medical Stores.
5. Director of Pharmaceutical Services Administration.
6. Director Assistant of Dasman Diabetic Institute.
7. Supervisor of Registration and Release of Drug and Food Control Administration.
8. Supervisor of Disposable Department of Central Medical Stores.
9. Supervisor of Drug Department of Central Medical Store.
10. Supervisor of Pharmaceutical Services Administration.
11. Head of Tablet Department of Central Medical Stores.
12. Head of Pharmaceutical services in Al Sabah Area.
13. Head of Drug Registration Department of Drug and Food Control Administration.
14. Head of Public Drug Inspection of Drug Inspection Administration.
15. Head of Pharmaceutical Services in Capital Area.
16. Head of Nurse Department in Al Sabah Hospital.
17. Head of Pharmacy in NBK Hospital.
18. Head of Imported Drug Release Department in Kuwait International Airport.
19. Head of Medicine Wards in Al Sabah Hospital.
20. Head of Pharmacy in Medicine Hospital.
21. Head of Pharmacy in Dermatology Hospital.
22. Head of Special Order Department in Central Medical Store.
23. Head of Diabetic Department in Dasman Diabetic Institute.
24. Vice Dean of Kuwait Pharmaceutical Faculty.
25. Head of Pharmaceutical Department of Kuwait Pharmaceutical Faculty.
26. Head of Pharmacy in Military Hospital.
27. Head of Pharmacy in Kuwaiti National Guard Clinic

As indicated the total number of senior staff interviewed were 27 from the 101 interviewed health professionals in the public sector (see the Table below, which shows the number of interviewed senior staff and their positions).

**Table 4.8: Number of Interviewed Senior Staff in Public Health Sector.**

| **Senior Staff Positions** | **No** |
|---|---|
| Assistant Under Secretary for Drug and Medical Supplies of KMOH | 1 |
| Directors of Public Heath Administrations | 5 |
| Supervisors of Public Heath Administrations | 4 |
| Head of Public Departments | 16 |
| Vice Dean of Kuwait Pharmaceutical Faculty | 1 |
| **Total** | **27** |

4.4.2 Interviews in the private sector

- In addition to the public sector, a number of senior managers in the private sector were interviewed in 10 pharmaceuticals companies and one private hospital:

1. Astra Zeneca Drug Company (Their Branch in Kuwait).
2. Merik Sharb and Domin – Al Humaizi Drug Company.
3. Sandos Drug Company (Their Branch in Kuwait).

4. Mohamed Naser Al Hajri Drug Company.
5. Pfizer – Safwan Drug Company.
6. Yiaco Drug Company.
7. Abbot – Al Mojil Drug Company.
8. Dunia Medical Drug Company.
9. Al Wazan Drug Company.
10. Boshehri Drug Company.
11. Royal Hayat Hospital (Private Hospital).

- The interviews also included a number of senior staff working in different places in the private sector.

The total interviewed senior staff was 16 from the 21 interviewed health professionals in the private sector, as listed below:

1. The Board Member of Royal Hayat Hospital (Private Hospital).
2. Regional Sales Manager in Yiaco Drug Company.
3. Key Account Manager in Yiaco Drug Company.
4. Sales Manager in Abbot – Al Mojil Drug Company.
5. OM Regional Manager Lower Gulf Countries in Al Wazan Drug Company.
6. District Sales Manager in Kuwait, Bahrain and Qatar.
7. Pharma Manager in Safwan Drug Company.
8. Sales Manager in Al Humaizi Drug Company.
9. Business Development Manager in Yiaco Drug Company.
10. Key Account Manager in Pfizer – Safwan Drug Company.
11. DRA Drug Regulatory Manager in MNHS Drug Company.
12. Area Sales Manager in all GCC countries in Astra Zenica.
13. Pharmacy Manager in Yiaco Drug Company.
14. Sales Supervisor Pharma Division in Boshehri Drug Company.
15. Field Force Supervisor.
16. Head of Sales Department in GCC for Sandoz Drug Company.

## 4.5 Descriptive Analysis

The work on the establishment of the National Drug Policy in Kuwait requires many areas of study and development. One of the important factors is the knowledge about the access to necessary information and data generation which can show the level of operation of the health care system. This would include the medical and pharmaceutical services and the health regulations and legislations in Kuwait. As indicated in the last section, it was important to take into account the views of the health care professionals and this was carried out in this study by building an information database from the questionnaire and interview procedure to take advantage of their experiences, opinions and recommendations. The results obtained are presented and discussed below.

The gender of the respondents is shown in Table 4.9, where the majority of the respondents were male (57.9%) and the rest (42.1%) female, but this does not reflect the health professionals' population where most managerial level staff is male. It was also easier to meet a male pharmacist because most female pharmacists refused to participate in the interview for matters relating to customs and traditions of Arab society and modesty.

**Table 4.9**

**Gender**

| | Frequency | Percent |
|---|---|---|
| **Male** | 70 | 57.9 |
| **Female** | 51 | 42.1 |
| **Total** | 121 | 100.0 |

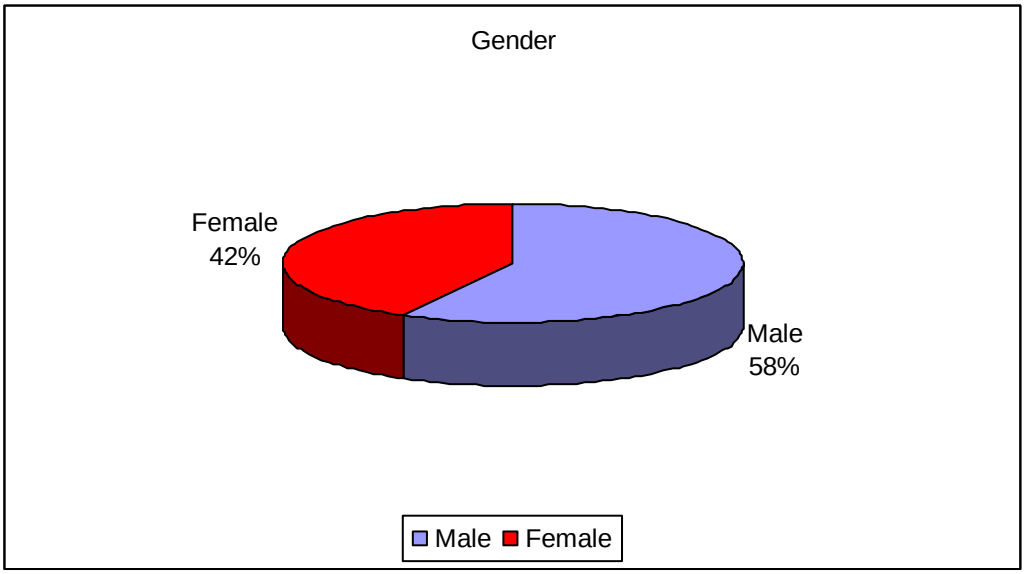


**Figure 4.2**

In selecting the interviewees, both the public and private sectors were considered but the bias was to the public sector; where there were 101 interviewees from the public sector and 20 from the private sector (See Table 4.10). The largest numbers of interviewees were chosen from the public sector because it contains the largest range of health professionals (pharmaceutical administration, pharmacies, hospitals, health clinics, health areas, research centres and the Kuwaiti Pharmaceutical Faculty).

**Table 4.10**

**Sector**

| | Frequency | Percent |
|---|---|---|
| **Public Sector** | 101 | 83.5 |
| **Private Sector** | 20 | 16.5 |
| **Total** | 121 | 100.0 |

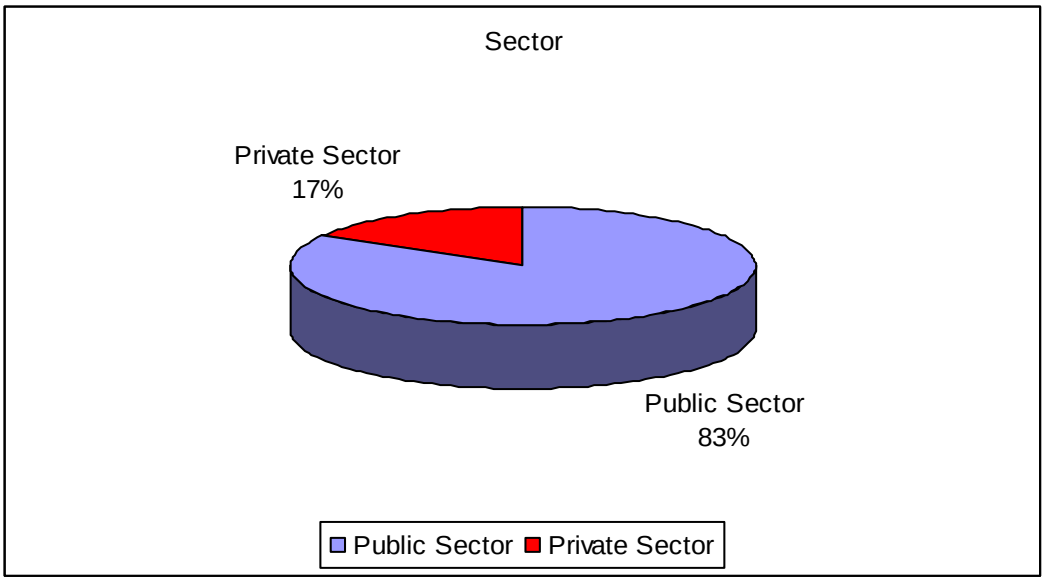


**Figure 4.3**

The professions of the interviewees' were: 88 pharmacists, 28 physicians and 5 nurses from 121 interviewees. From the 88 pharmacists, there were 2 pharmacists who had PhDs in the Pharmaceutical Sciences (Assistant Under-Secretary for Drug and Medical Supplies of KMOH and Vice Dean of Kuwait Pharmaceutical Faculty), and 1 professor of pharmaceutics (Head of Pharmaceutical Department of Kuwait Pharmaceutical Faculty). The largest number of interviewees chosen were pharmacists because they are mainly concerned with the issues, factors, nature and works of a future national drug policy (see Table 4.11 below).

The interviewees were distributed across different functions, including hospitals, health administration, drug companies, health clinics, research center and pharmaceutical faculty (see Table 4.12). This range was to take advantage of all the expertise and get the bulk of the information and requirements needed for the research project.

**Table 4.11**

**Profession**

| | Frequency | Percent |
|---|---|---|
| **Pharmacist** | 88 | 72.7 |
| **Physician** | 28 | 23.1 |
| **Nurse** | 5 | 4.1 |
| **Total** | 121 | 100.0 |

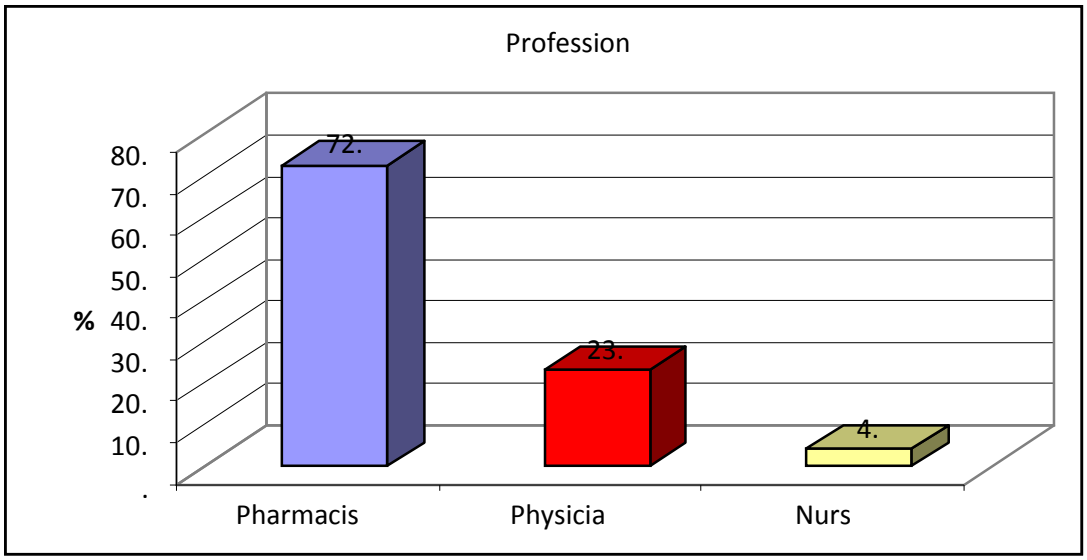


**Figure 4.4**

**Table 4.12**

**Place**

| | Frequency | Percent |
|---|---|---|
| **Hospital** | 69 | 57.0 |
| **Health Administration** | 18 | 14.9 |
| **Drug Company** | 20 | 16.5 |
| **Clinic** | 10 | 8.3 |
| **Research Center** | 2 | 1.7 |
| **University** | 2 | 1.7 |
| **Total** | 121 | 100.0 |

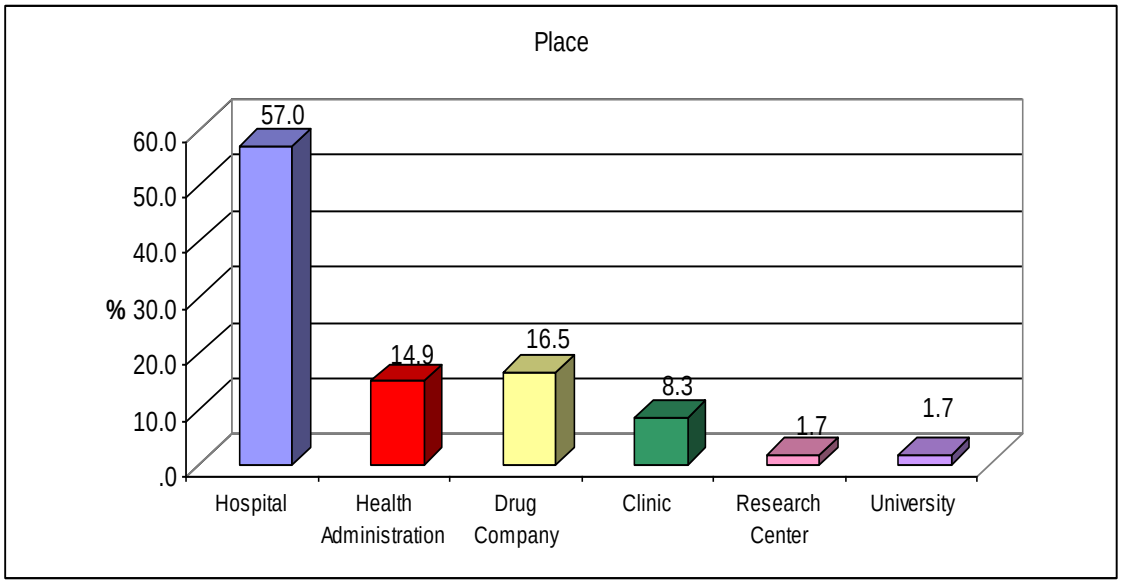


**Figure 4.5**

## 4.6 Questions asked at the interviews and the outcomes

The interview consisted of 12 questions which were related to the research project and covered all the parts of the health care system in Kuwait. The questions were designed to find out the main issues related to the health care system, to discuss these issues and then find possible suitable solutions for the issues and their requirements which could help in establishing a Kuwaiti National Drug Policy on valid grounds. Also they were designed to try to provide the viewpoints of senior health professionals so that the Kuwaiti Ministry of Health (KMOH) may consider establishing a NDP.

**Question 1:** “How important is having a NDP?”

All the 121 interviewees agreed that it is important that a NDP is developed as this would improve the health care system and is likely to establish an on-line system of regulations and legislation (see Table 4.13 below).

Question 1 included 5 answers which were divided into: Very Important, Important, Not Applicable, Not Important and Useless, to cover all the interviewees opinions’ and contentment with the point. From the 5 possible answers which could be chosen, all the health professionals gave the first 2 answers. This indicates that all the interviewees were convinced of the importance of having a National Drug Policy (See Appendix 1).

**Table 4.13 Question 1: How important is having a national drug policy?**

| | Frequency | Percent |
|---|---|---|
| **Very Important** | 107 | 88.4 |
| **Important** | 14 | 11.6 |
| **Total** | 121 | 100.0 |

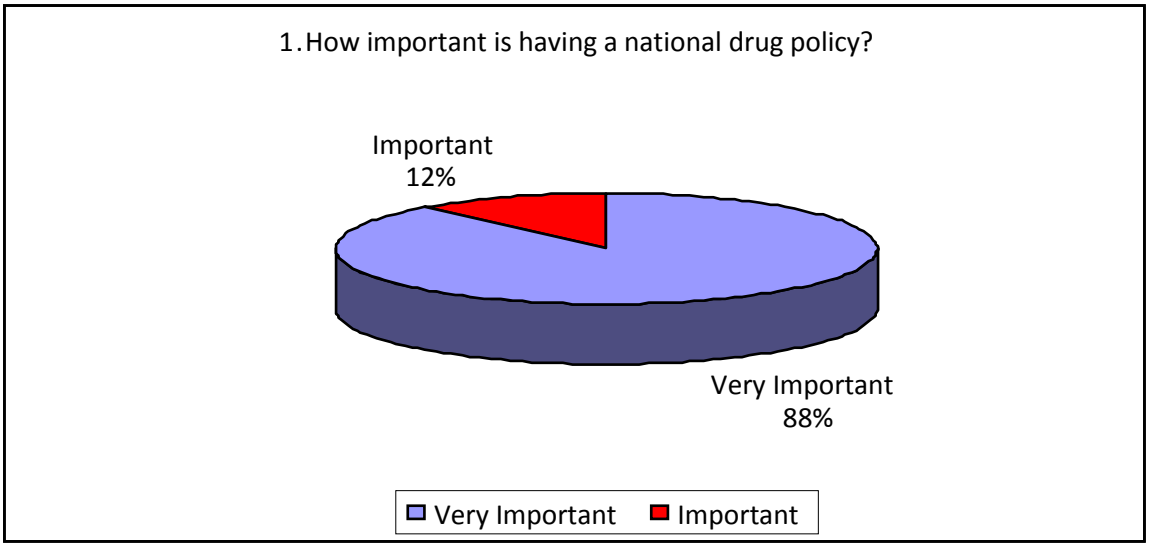


**Figure 4.6 Question 1: How important is having a national drug policy?**

- **Question 2:** “Do you think we can develop and improve the health care system in Kuwait?"

95.9% of the 121 interviewees answered that the health care system could be improved by establishing a NDP, and suggested that education for health professionals on all relevant regulatory affairs should be introduced. This should be done by improving the training programs. They also indicated that improving the software programs and establishing an electronic link between the administration,

hospitals and health clinics of the KMOH would improve the system and that further research centers should be established as well as an Essential Drug List. However 4.1% said that such development was not possible because of the lack of guidelines for the health sector and the unwillingness to make the decisions to improve the system (see Table 4.14 below).

**Table 4.14 Question 2: Do you think we can develop and improve the health care system in Kuwait?**

| | Frequency | Percent |
|---|---|---|
| **Yes** | 116 | 95.9 |
| **No** | 5 | 4.1 |
| **Total** | 121 | 100.0 |

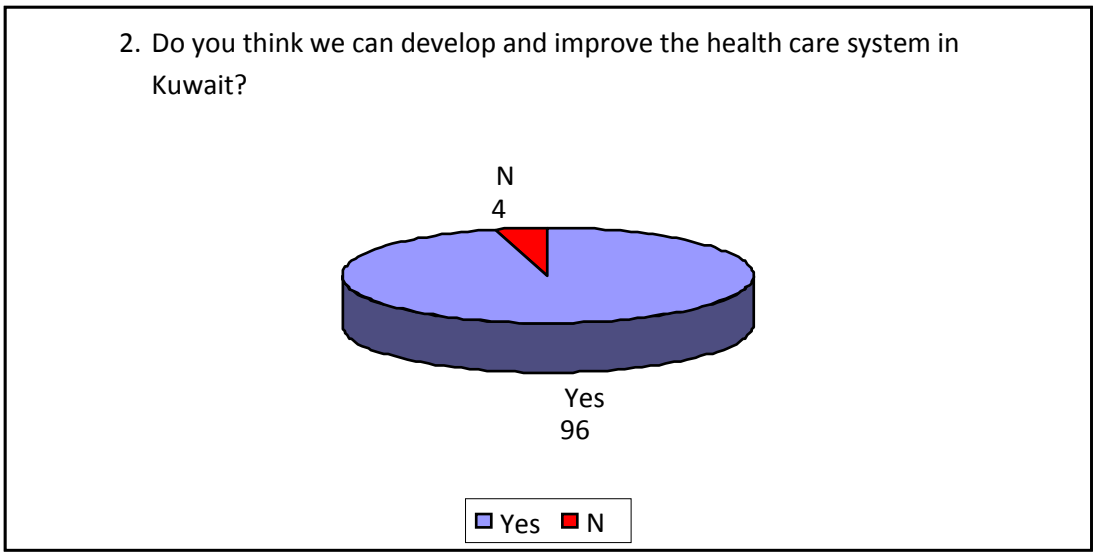


**Figure 4.7 Question 2: Do you think we can develop and improve the health care system in Kuwait?**

**- Question 3:**" Are there any issues of concern with the organization of the Health Care System in Kuwait?"

82.6% of the 121 interviewees indicated that Kuwait has issues in the health care system and provided the follow comments:

- Lack of knowledge of MOH regulators on the economics related to the system.
- Delays in the decision making process from regulators.
- Lack of centralization.
- Inadequate strict penalties for counterfeit drugs.
- A need for more hospitals and additional beds.
- The need for an increase in the number of health staff, particularly pharmacists and nurses.
- The need for an increase in information technology facilities in the KMOH.
- The need for more research centers because there is currently only one (Dasman Diabetes Institute).
- Lack of training programs and conferences for health professionals.
- The need for greater cooperation between the KMOH and Kuwait University to take advantage of their science research.
- Improve the Drug Release Department in Kuwait Airport by providing suitable staff to organize an electronic link system with the Kuwait Drug and Food Control Administration.

Only 7.4% of the 121 interviewees answered that there are no issues with the system, and in 9.9% of cases the answers were not considered applicable (see Table 4.15 below.)

**Table 4.15 Question 3: Are there any issues of concern with the organization of the health care system in Kuwait?**

| | Frequency | Percent |
|---|---|---|
| **Strongly Agree** | 35 | 28.9 |
| **Agree** | 65 | 53.7 |
| **Not Applicable** | 12 | 9.9 |
| **Disagree** | 5 | 4.1 |
| **Strongly Disagree** | 4 | 3.3 |
| **Total** | 121 | 100.0 |

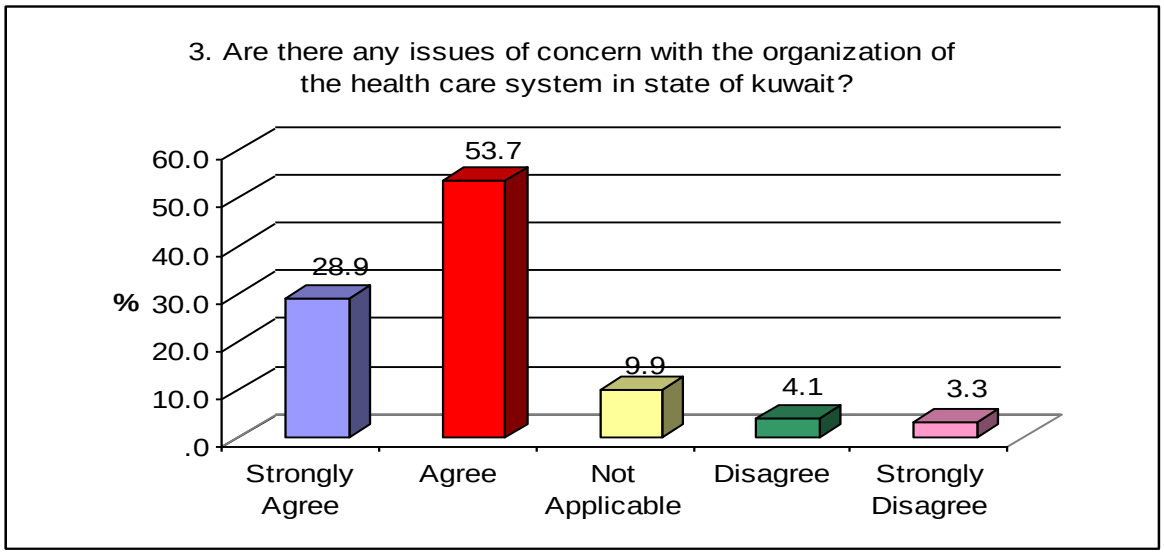


**Figure 4.8 Question 3:**

**Are there any issues of concern with the organization with the health care system in Kuwait?**

**- Question 4:** “In the public and private sectors, do you think we have enough control over regulation of the process associated with pharmaceuticals?”

55.4% of the 121 interviewees thought that in Kuwait there was enough control over the registration of pharmaceutical products and over their secondary control after licensing. They also suggested that there was enough inspection and administration being carried out which covers the auditing and monitoring of public and private pharmacies, medical stores and medical companies. The remaining 44.6% disagreed, indicating there is a lack of control over private pharmacies. This is because they think there are pharmacists in the private sector who are dispensing drugs without prescription or unregistered drugs for the patients and there are counterfeit drugs in the market place (see Table 4.16 below).

**Table 4.16 Question 4:**

**In the public and private sector, do you think we have enough control over regulation of the process associated with pharmaceuticals?**

| | Frequency | Percent |
|---|---|---|
| **Yes** | 67 | 55.4 |
| **No** | 54 | 44.6 |
| **Total** | 121 | 100.0 |

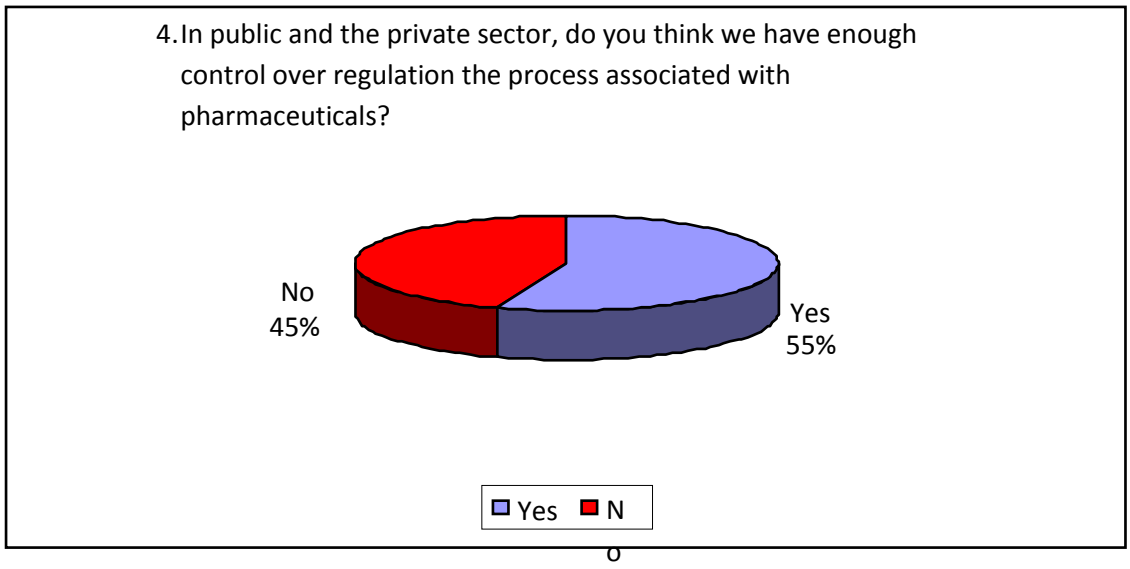


**Figure 4.9 Question 4:**

**In the public and private sector, do you think we have enough control over regulation of the process associated with pharmaceuticals?**

**- Question 5:** "Do you feel that the training of health professionals in the public and private sector is sufficient?"

64.5% of the 121 interviewees answered 'No' to this question and gave the reason that there is a lack of training programs for health professionals, especially after graduation from university. In addition there is a lack of new knowledge introduced through local and national health conferences and training programs. In this respect, since 1992 (after the Gulf War) the pharmaceutical training programs have no longer been running. However, it should be noted that in 2011 the KMOH started to cooperate with the Kuwaiti Pharmaceutical Faculty to prepare new training programs and to establish a new Department for training called the Clinical Pharmacy Department.

The other 35.5% of the 121 interviewees indicated that there is enough training programs (see Table 4.17).

**Table 4.17 Question 5:**

**Do you feel that the training of health professionals in the public and private sector is sufficient?**

| | Frequency | Percent |
|---|---|---|
| **Yes** | 43 | 35.5 |
| **No** | 78 | 64.5 |
| **Total** | 121 | 100.0 |

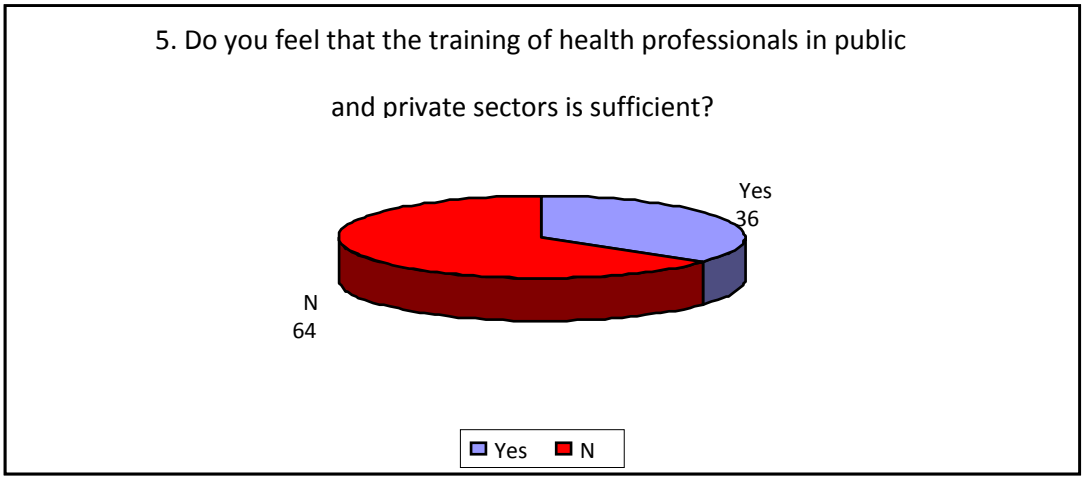


**Figure 4.10 Question 5:**

**Do you feel that the training of health professionals in the public and private sector is sufficient?**

**- Question 6:** "Do you think that the price range of medication in the private sector is publically acceptable?"

51.2% of the 121 interviewees disagreed and strongly disagreed that the price of medications in the private sector is acceptable when compared to other Gulf countries, e.g., in the Kingdom of Saudi Arabia (KSA). The prices in Kuwait are

three times higher. They also thought that the Pricing Department is not strict enough with the drug prices in the private sector. On the other hand, 35.6% said the prices are acceptable when compared to the prices in KSA. Although the prices are higher, this is related to a number of factors such as the larger population in KSA which makes bulk ordering medicines cheaper. In addition there is no pharmaceutical industry in Kuwait whereas there are many pharmaceutical companies in KSA and therefore competition exists and again the market size is much larger. Also, they mentioned that medicine costs are calculated against the USD and every six months the Pricing Department recalculates the drug prices according to the value of the USD. This controls and regulates the pricing better. On the other figures, 13.2% answered that the question was not applicable to them as they had no idea about the price range of medication in the private market (see Table 4.18 below).

**Table 4.18 Question 6:**

**Do you think that the price range of medication in the private sector is publically acceptable?**

| | Frequency | Percent |
|---|---|---|
| **Strongly Agree** | 10 | 8.3 |
| **Agree** | 33 | 27.3 |
| **Not Applicable** | 16 | 13.2 |
| **Disagree** | 34 | 28.1 |
| **Strongly Disagree** | 28 | 23.1 |
| **Total** | 121 | 100.0 |

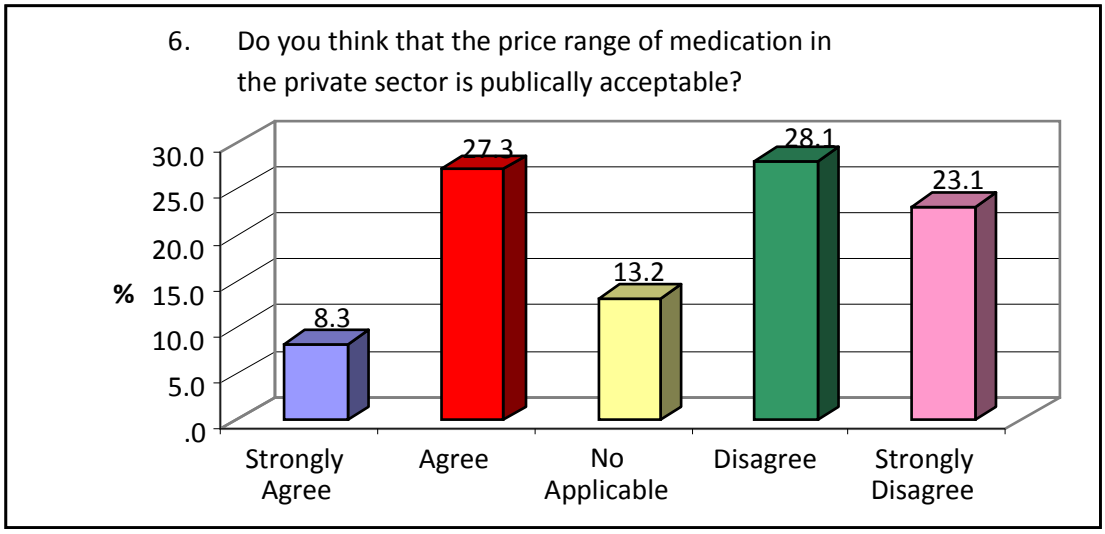


**Figure 4.11 Question 6:**

**Do you think that the price range of medication in the private sector is publically acceptable?**

**- Question 7:** "Do you think that there are any issues with access to quality, safety and efficacy of drugs?"

53.6% of the 121 interviewees answered that there are no issues with access to good quality, safe and efficacious drugs. The reasons given included that they thought the drugs procured in the public sector are of the best quality and medication is free for the citizens and residents. Other comments included that in the private market all the medicines are controlled by the KMOH as they must be registered and licensed by the Drug and Food Control Administration before they are sold in the open market. However 46.3% of the 121 interviewees suggested that there are issues and there should be improvements. The reasons given included that in the private sector there is a lack of control of non-prescription medicines, which includes antibiotics and sexual medicines (see Table 4.19 below).

**Table 4.19 Question 7:**

**Do you think that there are any issues with the access to quality, safe and effective drugs?**

| | Frequency | Percent |
|---|---|---|
| **Yes** | 56 | 46.3 |
| **No** | 65 | 53.7 |
| **Total** | 121 | 100.0 |

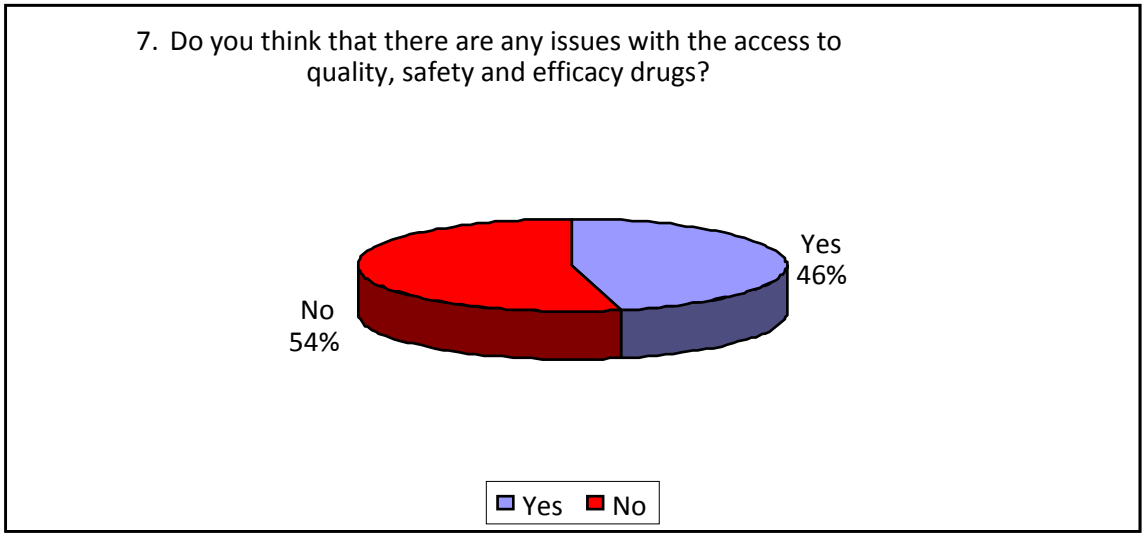


**Figure 4.12 Question 7:**

**Do you think that there are any issues with access to quality, safe and effective drugs?**

**- Question 8:** “Do you think that there is irrational use of drugs in Kuwait?”

86% of the 121 interviewees felt that there is a problem with irrational drug prescribing and use in Kuwait. This was suggested to occur mostly through self-medication, an example is the usage of an antibiotic without prescription and usage of sexual drugs without consultation with a physician. In addition, they suggested that compliance of patients is very low in Kuwait due to the weak health education, especially with the older patients (see Table 4.20 below).

**Table 4.20 Question 8:**

**Do you think that there is irrational use of drugs in Kuwait?**

| | Frequency | Percent |
|---|---|---|
| **Strongly Agree** | 55 | 45.5 |
| **Agree** | 49 | 40.5 |
| **Not Applicable** | 6 | 5.0 |
| **Disagree** | 8 | 6.6 |
| **Strongly Disagree** | 3 | 2.5 |
| **Total** | 121 | 100.0 |

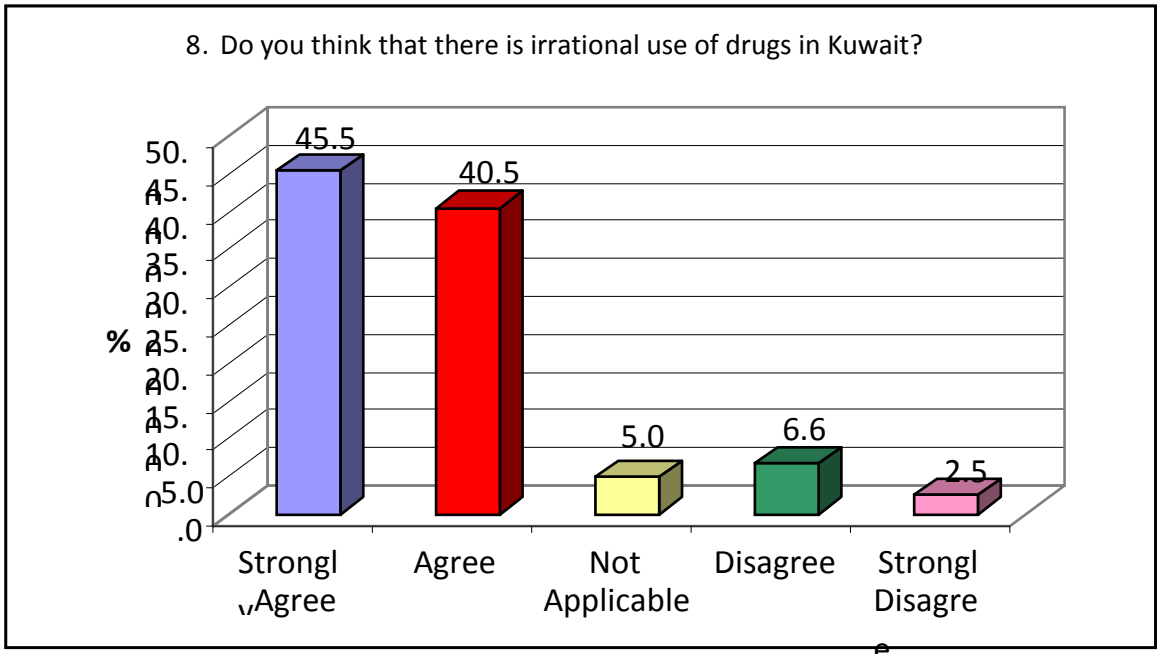


**Figure 4.13 Question 8:**

**Do you think that there is irrational use of drugs in Kuwait?**

**- Question 9:** "How important is having an Essential Drug List?"

95% of the 121 interviewees suggested that Kuwait should establish an Essential Drug List which would be based upon the needs of the state. The majority thought that an Essential Drug List would lead to savings in the national budget and reductions in the numbers of expired drugs held in the stores. Also, it could lead to better ways of determining the appropriate drug needs for the long term and also reduce any costs associated with adverse reactions, severe side effects and legal complications (see Table 4.21 below).

**Table 4.21 Question 9:**

**How important is having an Essential Drug List?**

| | Frequency | Percent |
|---|---|---|
| **Very Important** | 84 | 69.4 |
| **Important** | 31 | 25.6 |
| **Not Applicable** | 5 | 4.1 |
| **Not Important** | 1 | .8 |
| **Total** | 121 | 100.0 |

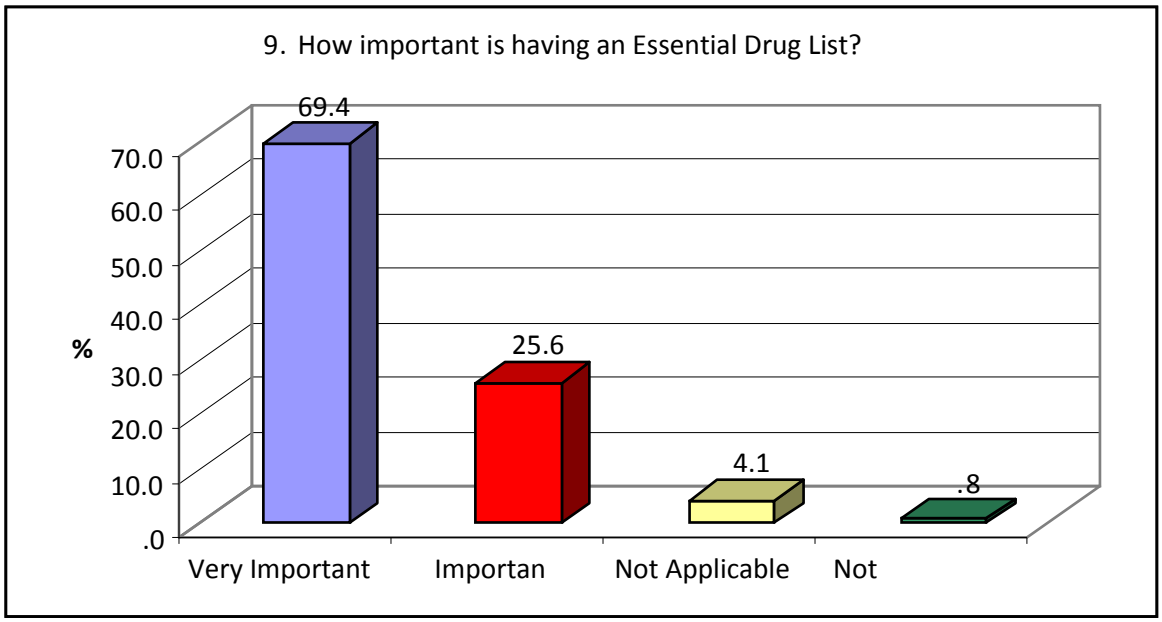


**Figure 4.14 Question 9: How important is having an Essential Drug List?**

**- Question 10:** "Do you think that Kuwait should develop its own pharmaceutical industry?"

82.6% of the 121 interviewees were in favour of developing a Kuwaiti pharmaceutical industry. One of the main reasons given was that it would secure the country's medicines resources by providing availability during emergencies and

war. Also it increases and improves the national sources of income and develops the pharmaceutical technologies.

However, 17.4% of the interviewers were against the proposal because they thought that Kuwait has too small a market to have many pharmaceutical companies and as well as the world is fairly small each country should do what they are good at. Also, a pharmaceutical industry needs high level technology, research centers and trained staff to ensure the production of quality drugs but all these are absent in Kuwait (see Table 4.22).

**Table 4.22 Question 10:**

**Do you think that Kuwait should develop its own pharmaceutical industry?**

| | Frequency | Percent |
|---|---|---|
| **Yes** | 100 | 82.6 |
| **No** | 21 | 17.4 |
| **Total** | 121 | 100.0 |

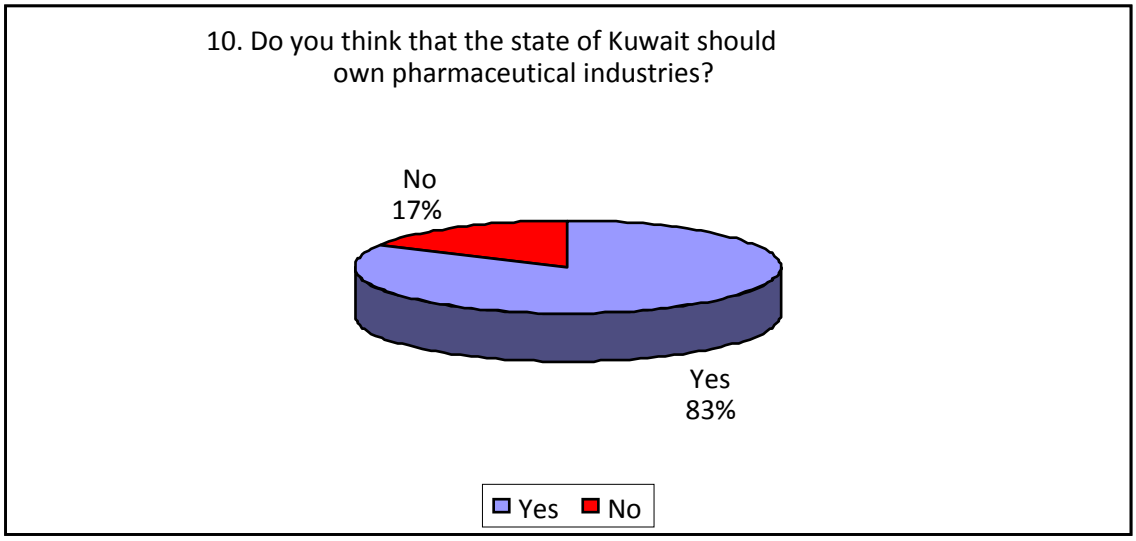


**Figure 4.15 Question 10:**

**Do you think that Kuwait should develop its own pharmaceutical industry?**

**- Question 11:** "Do you think it is time to establish a NDP in Kuwait?"

95% of the 121 interviewees agreed that it would be beneficial to establish a NDP in Kuwait. It was suggested that it is likely to improve the health system and develop the health services in Kuwait. Only 5% of the interviewees disagreed, stating that the KMOH did not have enough power, and neither would they be able to make the decisions and manage such a major development as establishing a NDP in Kuwait at this moment (See Table 4.23 below).

**Table 4.23 Question 11:**

**Do you think it is time to establish a national drug policy in Kuwait?**

| | Frequency | Percent |
|---|---|---|
| **Yes** | 115 | 95.0 |
| **No** | 6 | 5.0 |
| **Total** | 121 | 100.0 |

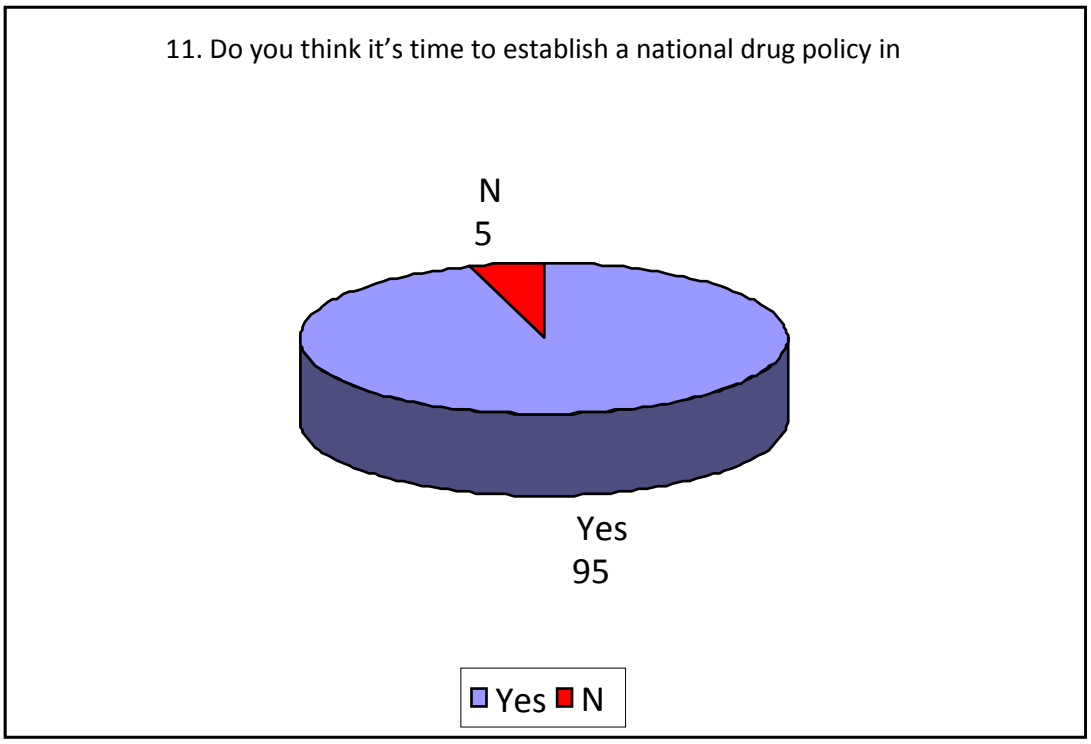


**Figure 4.16 Question 11:**

**Do you think it is time to establish a national drug policy in Kuwait?**

## 4.7 Methods of evaluating the Data: Cross Tabulation

### 4.7.1 Quantitative Analysis

In this analysis, 5 hypotheses were used to analyze the collected data from the questionnaire. These are described below.

**Results of the first hypothesis**

This hypothesis provided that no statistically significant differences were present between the sample responses to the questions in the questionnaire:

1. How important is having a NDP?
2. Do you think we can develop and improve the health care system in Kuwait?
3. Are there any issues of concern with the organization of the health care system in Kuwait?
4. In the public and private sectors, do you think we have enough control over regulating the process associated with pharmaceuticals?
5. Do you feel that the training of health professionals in the public and private sector is sufficient?
6. Do you think that the price range of medication in the private sector is publically acceptable?
7. Do you think that there are any issues with access to quality, safe and effective drugs?
8. Do you think that there is irrational use of drugs in Kuwait?
9. How important is having an Essential Drug List?
10. Do you think that Kuwait should develop its own pharmaceutical industry?
11. Do you think it is time to establish a NDP in Kuwait?

To validate this hypothesis, the Chi-Square Test ( $x^2$ ) was used (this is a widely used non-parametric statistical test that describes the magnitude of discrepancy

between the observed data and the data expected to be obtained with a specific hypothesis) to identify the significance of the differences between the obtained frequencies from the research sample on the responses of the questions of the questionnaire. A chi-squared test is constructed through sample variance or from the sum of squared errors in a data set, and refers to any statistical hypothesis test where the sampling distribution of a test statistic follows a chi-square distribution when the null is true (Zibran, 2015). It is a common non-parametric statistical method used when data consists of counts, or a frequency, and where the probability of association between independent facts is sought.

Again, chi-square tests rely upon the assumption that data is normally distributed. These tests can be useful for analysing variance in a normal population or for the analysis of categorical data. For example, imagine a study analysing the survival times of patients suffering from four different types of blood cancer, and how it was related to four categorical variables, such as the level of household income, or the number of cigarettes smoked per day in a smoking cohort. Here, the chi-squared test can be used to identify the most likely correlates amongst the data, and is useful for stratifying the patient cohort (Zibran, 2015). The result is set out in the table below (Page 120, 121 and 122).

**Table 4.24 The Result of the use of Chi-Square Test ( $x^2$) to identify the significant difference between the frequency of the research sample responses to the questions of the questionnaire**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of significance* |
|---|---|---|---|---|
| *1.* | *Very Important* | *107*<br>*88.4* | *71.48* | *0.01** |
| | *Important* | *14*<br>*11.6* | | |
| *2.* | *Yes* | *116*<br>*95.9* | *101.82* | *0.01** |
| | *No* | *5*<br>*4.1* | | |
| *3.* | *Strongly Agree* | *35*<br>*28.9* | *66.61* | *0.01*** |
| | *Agree* | *65*<br>*53.7* | | |
| | *Not Applicable* | *12*<br>*9.9* | | |
| | *Disagree* | *9*<br>*7.4* | | |
| *4.* | *Yes* | *67*<br>*55.4* | *1.40* | *0.30** |
| | *No* | *54*<br>*44.6* | | |

**Follow Table 4.24 The Result of the use of Chi-Square Test ( $x^2$) to identify the significant difference between the frequency of the research sample responses to the questions of the questionnaire**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of significance* |
|---|---|---|---|---|
| *5.* | *Yes* | *43*<br>*35.5* | *10.12* | *0.01 ** |
| | *No* | *78*<br>*64.5* | | |
| *6.* | *Strongly Agree* | *10*<br>*8.3* | *20.98* | *0.01 **** |
| | *Agree* | *33*<br>*27.3* | | |
| | *Not Applicable* | *16*<br>*13.2* | | |
| | *Disagree* | *34*<br>*28.1* | | |
| | *Strongly Disagree* | *28*<br>*23.1* | | |
| *7.* | *Yes* | *56*<br>*46.3* | *0.66* | *0.50 *** |
| | *No* | *65*<br>*53.7* | | |

**Follow Table 4.24 The Result of the use of Chi-Square Test ( $x^2$ ) to identify the significant difference between the frequency of the research sample responses to the questions of the questionnaire**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of significance* |
|---|---|---|---|---|
| *8.* | *Strongly Agree* | *55* *45.5* | *63.56* | *0.01 *** |
| | *Agree* | *49* *40.5* | | |
| | *Not Applicable* | *6* *5.0* | | |
| | *Disagree* | *11* *9.1* | | |
| *9.* | *Very Important* | *84* *69.4* | *78.67* | *0.01 ***** |
| | *Important* | *31* *25.6* | | |
| | *Not Applicable* | *6* *4.9* | | |
| *10.* | *Yes* | *100* *82.6* | *51.58* | *0.01 ** |
| | *No* | *21* *17.4* | | |
| *11.* | *Yes* | *115* *95.0* | *98.20* | *0.01 ** |
| | *No* | *6* *5.0* | | |

*$x^2$ (1,0.01)=6.635 **$x^2$ (3,0.01)= 11.345 ***$x^2$ (4,0.01)= 13.277

****$x^2$ (2,0.01)=9.210 *$x^2$ (1,0.30)=1.074 **$x^2$ (1,0.50)=0.455

This table shows the following:

1. There was a significant difference at the level (0.01) between the responses of the research sample to question 1 with highest frequency given to “very important”, and this means that the research sample indicated that the existence of a NDP in Kuwait is very important. In addition the proportion of total confidence in the outcome of question 1 reached 99% (0.01).
2. There was a significant difference at the level (0.01) between the responses of the research sample to question 2 with highest frequency given to response “yes”, and this means that the research sample indicated that the health care system in Kuwait could be developed and improved. In addition, the proportion of total confidence in the outcome of question 2 reached 99% (0.01).
3. There was a significant difference at the level (0.01) between the responses of the research sample to question 3 with highest frequency given to the response “agree”, and this means that the research sample indicated that there are issues of concern with the health care system in Kuwait. In addition, the proportion of total confidence in the outcome of question 3 reached 99% (0.01).
4. There was a significant difference at the level (0.30) between the responses of the research sample to question 4 with highest frequency given to the response “yes”, and this means that the research sample suggested that there is enough control over public and private pharmaceutical sectors in Kuwait. In addition, the proportion of total confidence in the outcome of question 4 reached only 70% (0.30).
5. There was a significant difference at the level (0.01) between the responses of the research sample to question 5 with highest frequency given to the response “no”, and this means that the research sample indicated that the number of training programs for health professionals (physicians, pharmacists and nurses) in the public and private sector is insufficient. In addition the proportion of total confidence in the outcome of the question 5 reached 99% (0.01).

6. There was a significant difference at the level (0.01) between the responses of the research sample to question 6 in with highest frequency given to the response “strongly disagree”, and this means that the research sample agreed that the price range of medication in the private sector is not acceptable and exaggerated. In addition, the proportion of total confidence in the outcome of question 6 reached 99% (0.01).
7. There was a significant difference at the level (0.50) between the responses of the research sample to question 7 with highest frequency given to the response “no”, and this means that the research sample accepted that there are no issues with access to good quality, safe and efficacious drugs. In addition, the proportion of total confidence in the outcome of question 7 reached only 50% (0.50).
8. There was a significant difference at the level (0.01) between the responses of the research sample to question 8 with highest frequency given to the response “strongly agree”, and this means that the research sample agreed that there is irrational use of drugs in the state. In addition, the proportion of total confidence in the outcome of question 8 reached 99% (0.01).
9. There was a significant difference at the level (0.01) between the responses of the research sample to question 9 with highest frequency given to the response “very important”, and this means that the research sample indicated that the existence of an Essential Drug List is very important. In addition, the proportion of total confidence in the outcome of question 9 reached 99% (0.01).
10. There was a significant difference at the level (0.01) between the responses of the research sample to question 10 in with highest frequency given to the response “yes”, and this means that the research sample indicated that Kuwait could develop its own pharmaceutical industry. In addition, the proportion of total confidence in the outcome of question 10 reached 99% (0.01).
11. There was a significant difference at the level (0.01) between the responses of the research sample to question 11 with highest frequency given to the response “yes”, and this means that the research sample suggested that the

establishment of a NDP in the country would be useful at the current stage. In addition, the proportion of total confidence in the outcome of question 11 reached 99% (0.01).

Based on the information above, it can be summarized that in question 4 the level of confidence in the outcome of the question reached 70%, while in question 7 the level of confidence reached 50%; with the rest of the questions (1, 2, 3, 5, 6, 8, 9, 10 and 11) it reached 99%. As such, the results indicate that all the research sample responses were not subjected to chance, but it were deliberately, in which the responses showed cognition, understanding and awareness.

**Results of the second hypothesis**

This hypothesis provided that there is no statistically significant difference between the sample responses to the questions in the questionnaire based on gender. To validate this hypothesis, the One Way Analysis of Variance method was used in relation to the degrees obtained by the male and female participants in the questionnaire. This test is commonly used to compare differences between three (or more) groups of unrelated values, although it can also be used on two data sets (Daya, 2003).The result is observed in the table below (Page 126, 127 and 128).

**Table 4.25 Result of the use of One Way Analysis of Variance method to the degrees obtained by the male and female participants to the questions of the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *1.* | *Between Groups* | *35.68* | *1* | *35.68* | *1.61* | *No significance* |
| | *Within Groups (error)* | *2637.04* | *119* | *22.16* | | |
| | *Total* | *2672.72* | *120* | | | |
| *2.* | *Between Groups* | *35.65* | *1* | *35.65* | *1.14* | *No significance* |
| | *Within Groups (error)* | *3721.13* | *119* | *31.27* | | |
| | *Total* | *3756.78* | *120* | | | |
| *3.* | *Between Groups* | *36.51* | *1* | *36.51* | *1.00* | *No significance* |
| | *Within Groups (error)* | *4344.69* | *119* | *36.51* | | |
| | *Total* | *4381.20* | *120* | | | |
| *4.* | *Between Groups* | *19.13* | *1* | *19.13* | *0.95* | *No significance* |
| | *Within Groups (error)* | *2396.66* | *119* | *20.14* | | |
| | *Total* | *2415.79* | *120* | | | |
| *5.* | *Between Groups* | *20.36* | *1* | *20.36* | *1.06* | *No significance* |
| | *Within Groups (error)* | *2285.99* | *119* | *19.21* | | |
| | *Total* | *2306.35* | *120* | | | |

**Follow Table 4.25 Result of the use of One Way Analysis of Variance method to the degrees obtained by the male and female participants to the questions of the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *6.* | *Between Groups* | *30.99* | *1* | *30.99* | *1.21* | *No significance* |
| | *Within Groups (error)* | *3047.59* | *119* | *25.61* | | |
| | *Total* | *3078.58* | *120* | | | |
| *7.* | *Between Groups* | *24.30* | *1* | *24.30* | *0.72* | *No significance* |
| | *Within Groups (error)* | *4016.25* | *119* | *33.75* | | |
| | *Total* | *4040.55* | *120* | | | |
| *8.* | *Between Groups* | *11.96* | *1* | *11.96* | *0.61* | *No significance* |
| | *Within Groups (error)* | *2332.40* | *119* | *19.60* | | |
| | *Total* | *2344.36* | *120* | | | |
| *9.* | *Between Groups* | *15.79* | *1* | *15.79* | *0.86* | *No significance* |
| | *Within Groups (error)* | *2184.84* | *119* | *18.36* | | |
| | *Total* | *2200.63* | *120* | | | |
| *10.* | *Between Groups* | *60.97* | *1* | *60.97* | *2.30* | *No significance* |
| | *Within Groups (error)* | *3154.69* | *119* | *26.51* | | |
| | *Total* | *3215.66* | *120* | | | |

**Follow Table 4.25 Result of the use of One Way Analysis of Variance method to the degrees obtained by the male and female participants to the questions of the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *11.* | *Between Groups* | *44.02* | *1* | *44.02* | *2.01* | *No significance* |
| | *Within Groups (error)* | *2606.10* | *119* | *21.90* | | |
| | *Total* | *2650.12* | *120* | | | |
| *All Ques.* | *Between Groups* | *97.59* | *1* | *97.59* | *2.11* | *No significance* |
| | *Within Groups (error)* | *5503.75* | *119* | *46.25* | | |
| | *Total* | *5601.34* | *120* | | | |

* $F(1,119,0.05)=3.92$.

It can be seen from the table above that there is no significant difference between the responses of the research sample to the questions in the questionnaire or on its total degrees due to gender.

**Results of the third hypothesis**

This hypothesis provided the indication that there is no statistically significant difference between the sample responses to the questions in the questionnaire due to sector differences (public and private).

To validate this hypothesis, the One Way Analysis of Variance method was used to examine the degrees obtained by the public and private sector participants to the questions in the Questionnaire. The result can be observed in the table below (Page 129, 130 and 131).

**Table 4.26 Results of the use of One Way Analysis of Variance method to the degrees obtained by the public and private sector participants to the questions in the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *1.* | *Between Groups* | *38.09* | *1* | *38.09* | *1.12* | *No significance* |
| | *Within Groups (error)* | *4047.19* | *119* | *34.01* | | |
| | *Total* | *4085.28* | *120* | | | |
| *2.* | *Between Groups* | *83.46* | *1* | *83.46* | *1.98* | *No significance* |
| | *Within Groups (error)* | *5015.85* | *119* | *42.15* | | |
| | *Total* | *5099.31* | *120* | | | |
| *3.* | *Between Groups* | *137.03* | *1* | *137.03* | *4.12* | *0.05** |
| | *Within Groups (error)* | *3957.94* | *119* | *33.26* | | |
| | *Total* | *4094.97* | *120* | | | |
| *4.* | *Between Groups* | *93.91* | *1* | *93.91* | *2.10* | *No significance* |
| | *Within Groups (error)* | *5321.68* | *119* | *44.72* | | |
| | *Total* | *5415.59* | *120* | | | |

**Follow Table 4.26 Results of the use of One Way Analysis of Variance method to the degrees obtained by the public and private sector participants to the questions in the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *5.* | *Between Groups* | *47.78* | *1* | *47.78* | *1.68* | *No significance* |
| | *Within Groups (error)* | *3384.36* | *119* | *28.44* | | |
| | *Total* | *3432.14* | *120* | | | |
| *6.* | *Between Groups* | *96.91* | *1* | *96.91* | *2.12* | *No significance* |
| | *Within Groups (error)* | *5439.49* | *119* | *45.71* | | |
| | *Total* | *5536.40* | *120* | | | |
| *7.* | *Between Groups* | *51.43* | *1* | *51.43* | *1.82* | *No significance* |
| | *Within Groups (error)* | *3362.94* | *119* | *28.26* | | |
| | *Total* | *3414037* | *120* | | | |
| *8.* | *Between Groups* | *136.19* | *1* | *136.19* | *4.28* | *No significance* |
| | *Within Groups (error)* | *3786.58* | *119* | *31.82* | | |
| | *Total* | *3922.77* | *120* | | | |
| *9.* | *Between Groups* | *37.90* | *1* | *37.90* | *1.66* | *No significance* |
| | *Within Groups (error)* | *2716.77* | *119* | *22.83* | | |
| | *Total* | *2754.07* | *120* | | | |

**Follow Table 4.26 Results of the use of One Way Analysis of Variance method to the degrees obtained by the public and private sector participants to the questions in the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *10.* | *Between Groups* | *56.51* | *1* | *56.51* | *1.79* | *No significance* |
| | *Within Groups (error)* | *3756.83* | *119* | *31.57* | | |
| | *Total* | *3813.34* | *120* | | | |
| *11.* | *Between Groups* | *56.22* | *1* | *56.22* | *2.12* | *No significance* |
| | *Within Groups (error)* | *3155.88* | *119* | *26.52* | | |
| | *Total* | *3212.10* | *120* | | | |
| *All Ques.* | *Between Groups* | *54.51* | *1* | *54.51* | *1.31* | *No significance* |
| | *Within Groups (error)* | *4951.59* | *119* | *41.61* | | |
| | *Total* | *5006.10* | *120* | | | |

∗ *F(1,119,0.05)=3.92.*

It can be seen from the table above that there is no significant difference between the responses of the research sample to the questions (1, 2, 4, 5, 6, 7, 9, 10 and 11) or on its total degrees due to sector (in which the participants work) differences. However, statistically significant differences were present between the responses of the research sample to questions (3 and 8) based on sector difference. In order to identify the significant differences between sector medians for questions 3 and 8, the T. Test was used to determine whether two sets of (normally distributed) data are different from each other (or have different average values), and therefore, is central to basic research applications (Kim, 2015). T-tests are widely applied, and many variations of the test exist, each designed to deal

with different dataset features and hypothesis testing scenarios. In essence they compare means between different data sets, and can compare data to hypothesised values (one-sample tests) or other data sets (in two-sample tests). More specifically, t-tests refer to any statistical hypotheses where the test statistic follows a student's t-distribution under conditions of the null hypothesis; data falling into a non-normal distribution will lead to test inaccuracy (Main and Ogaz, 2016). (See table below).

**Table 4.27 Results from the use of T. Test, and the significant differences between the means of the public and private sector on questions 3 and 8.**

| *No. 0f Ques.* | *Public N(101)* | | *Private N(20)* | | *T Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| | *M* | *ST* | *M* | *ST* | | |
| *3* | *4.07* | *0.16* | *3.60* | *0.24* | *6.91* | *0. 01** |
| *8* | *4.27* | *0.25* | *3.65* | *0.28* | *12.40* | *0.01** |

**T(119,0.01)=2.60*

This table shows that there were significant differences at the level (0.01) in the response to questions 3 and 8 of the questionnaire. These were that:

- The health care system in Kuwait suffers from issues in both the public and private sectors but the interviewees (health professionals) from the public sector indicated and agreed about the existence of health issues in the country more than the interviewees from the private sector. In Question 3, the mean degree (M) of the public sector (4.07) was higher than the M of the private sector (3.60).
- There is a problem with irrational drug prescribing and use in Kuwait. The responses of the interviewees from the public sector which indicated the existence of this issue in question 8 were greater than the responses in the private sector –the M of the public sector (4.27) was also greater than the M of the private sector (3.65).

**Results of the fourth hypothesis**

This hypothesis indicated that there is no statistically significant difference between the sample responses to the questions in the Questionnaire due to the different profession of the interviewees (pharmacists, physicians and nurses).

To validate this hypothesis, the One Way Analysis of Variance method was used to examine the degrees of the pharmacists, physicians and nurses participants. The result can be observed in the table below (page 133, 134 and 135).

**Table 4.28 Results of the use of One Way Analysis of Variance method to the degrees of the participants (pharmacists, physicians and nurses) to the questions in the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *1.* | *Between Groups* | *53.42* | *2* | *26.71* | *2.40* | *No significance* |
| | *Within Groups (error)* | *1313.34* | *118* | *11.13* | | |
| | *Total* | *1366.76* | *120* | | | |
| *2.* | *Between Groups* | *12.86* | *2* | *6.43* | *3.20* | *0.05*** |
| | *Within Groups (error)* | *237.18* | *118* | *2.01* | | |
| | *Total* | *250.04* | *120* | | | |
| *3.* | *Between Groups* | *35.90* | *2* | *17.95* | *5.61* | *0.01** |
| | *Within Groups (error)* | *661.98* | *118* | *3.2* | | |
| | *Total* | *697.88* | *120* | | | |

**Follow Table 4.28 Results of the use of One Way Analysis of Variance method to the degrees of the participants (pharmacists, physicians and nurses) to the questions in the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *4.* | *Between Groups* | *10.24* | *2* | *5.12* | *3.20* | *0.05*** |
| | *Within Groups (error)* | *188.80* | *118* | *1.60* | | |
| | *Total* | *199.04* | *120* | | | |
| *5.* | *Between Groups* | *31.42* | *2* | *15.71* | *2.61* | *No significance* |
| | *Within Groups (error)* | *710.36* | *118* | *6.02* | | |
| | *Total* | *741.78* | *120* | | | |
| *6.* | *Between Groups* | *23.46* | *2* | *11.73* | *2.20* | *No significance* |
| | *Within Groups (error)* | *628.94* | *118* | *5.33* | | |
| | *Total* | *652.40* | *120* | | | |
| *7.* | *Between Groups* | *18.54* | *2* | *9.27* | *2.01* | *No significance* |
| | *Within Groups (error)* | *543.98* | *118* | *4.61* | | |
| | *Total* | *562.52* | *120* | | | |
| *8.* | *Between Groups* | *25.42* | *2* | *12.71* | *4.89* | *0.01*** |
| | *Within Groups (error)* | *306.80* | *118* | *2.6* | | |
| | *Total* | *332.22* | *120* | | | |

**Follow Table 4.28 Results of the use of One Way Analysis of Variance method to the degrees of the participants (pharmacists, physicians and nurses) to the questions in the questionnaire**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *9.* | *Between Groups* | *25.68* | *2* | *12.84* | *2.21* | *No significance* |
| | *Within Groups (error)* | *685.58* | *118* | *5.81* | | |
| | *Total* | *711.26* | *120* | | | |
| *10.* | *Between Groups* | *10.66* | *2* | *5.33* | *3.81* | *0.05*** |
| | *Within Groups (error)* | *165.20* | *118* | *1.40* | | |
| | *Total* | *175.86* | *120* | | | |
| *11.* | *Between Groups* | *13.60* | *2* | *6.80* | *1.89* | *No significance* |
| | *Within Groups (error)* | *435.42* | *118* | *3.69* | | |
| | *Total* | *449.02* | *120* | | | |
| *All Ques.* | *Between Groups* | *7.74* | *2* | *3.87* | *3.20* | *0.05*** |
| | *Within Groups (error)* | *142.78* | *118* | *1.21* | | |
| | *Total* | *150.52* | *120* | | | |

**F( 2,118,0.01)= 4.78*

*** F (2,118,0.05)= 3.07*

This table shows that:

1. There were significant differences at the level (0.01) between the responses of the research sample to the questions (3 and 8) due to the different professions of the interviewees.
2. There were significant differences at the level (0.05) between the responses of the research sample to the questions (2, 4 and 10) and the total degrees of the questionnaire due to the different professions of the interviewees.
3. There were no significant differences between the responses of the research sample to the questions (1, 5, 6, 7, 9 and 11) and the total degrees of the questionnaire due to the different professions of the interviewees. In addition, and to identify the significant differences between median degrees (for pharmacists, physicians and nurses) for questions (1, 5, 6, 7, 9 and 11), the Scheffe Method was used (see table below). The Scheffe test is a post-hoc test used in the analysis of variance (Curtis, et al., 2015). It is a test that usually used after running ANOVA test and got a significant statistical result (rejected null hypothesis) to find out which pairs of means are significant (Williams and Abdi, 2010). The Scheffe test is the most flexible three mean comparisons test, however, it has the lowest statistical power (Williams and Abdi, 2010).

**Table 4.29 Results of the use of the Scheffe Method and its significant differences between the means of interviewees (pharmacists, physicians and nurses) in question 2 of the questionnaire.**

| *Question No* | *Profession* | *Pharmacist* | *Physician* | *Nurse* |
|---|---|---|---|---|
| *2* | *Pharmacist M(1.97)* | -- | | |
| | *Physician M(1.93)* | *0.05* | -- | |
| | *Nurse M(0.36)* | *1.61* | *1.63* | -- |

*Scheffe Range = 0.992*

The previous table shows that:

1. There were no significant differences between the participants (pharmacists and physicians) as to whether the health care system in Kuwait could be developed and improved.
2. There were significant differences at the level (0.05) between the participants (pharmacists and nurses) over agreement that the health care system in Kuwait could be developed and improved. However, the result was in favour of pharmacists.
3. There were significant differences at the level (0.05) between the participants (physicians and nurses) in agreeing that the health care system in Kuwait could be developed and improved.

**Table 4.30 Results of the use of Scheffe Method and its significant differences between the means of interviewees (pharmacists, physicians and nurses) on question 3 of the questionnaire.**

| *Question No* | *Profession* | *Pharmacist* | *Physician* | *Nurse* |
|---|---|---|---|---|
| *3* | *Pharmacist M(3.92)* | -- | | |
| | *Physician M(4.32)* | *0.04* | -- | |
| | *Nurse M(0.64)* | *3.28* | *3.68* | -- |

Scheffe Range = 1.580

This table shows that:

1. There were no significant differences between the participants (Pharmacists and Physicians) on whether Kuwait has issues in the health care system.
2. There were significant differences at the level (0.01) between the participants (pharmacists and nurses) in agreeing that Kuwait has issues in the health care system. However, the result was in favour of pharmacists.
3. There were significant differences at the level (0.01) between the participants (physicians and nurses) in agreeing that the Kuwait has issues in the health care system. However, the result was in favour of physicians.

**Table 4.31 Result of the use of the Scheffe Method and its significant differences between the means of interviewees (pharmacists, physicians and nurses) on question 4 of the questionnaire.**

| *Question No* | *Profession* | *Pharmacist* | *Physician* | *Nurse* |
|---|---|---|---|---|
| *4* | *Pharmacist M(1.61)* | *--* | | |
| | *Physician M(1.29)* | *0.32* | *--* | |
| | *Nurse M(0.36)* | *1.25* | *0.93* | *--* |

*Scheffe Range = 0.893*

This table shows that:

1. There were no significant differences between the participants (pharmacists and physicians) who both thought that in Kuwait there was enough control over the pharmaceutical sector.
2. There were significant differences at the level (0.05) between the participants (pharmacists and nurses) in agreeing that in Kuwait there was enough control over the pharmaceutical sector. However the result was in favour of pharmacists.
3. There were significant differences at the level (0.05) between the participants (physicians and nurses) in agreeing that in Kuwait there was enough control over the pharmaceutical sector. However the result was in favour of physicians.

**Table 4.32 Results from use of the Scheffe Method and its significant differences between the means of interviewees (pharmacists, physicians and nurses) on question 8 of the questionnaire.**

| *Question No* | *Profession* | *Pharmacist* | *Physician* | *Nurse* |
|---|---|---|---|---|
| *8* | *Pharmacist M(4.17)* | *--* | | |
| | *Physician M(4.25)* | *0.08* | *--* | |
| | *Nurse M(0.64)* | *3.53* | *3.61* | *--* |

*Scheffe Range = 1.421*

This table shows that:

1. There were no significant differences between the participants (pharmacists and physicians) and suggested that Kuwait should establish an Essential Drug List which would be based upon the needs of the state.
2. There were significant differences at the level (0.01) between the participants (pharmacists and nurses) in agreeing that Kuwait should establish an Essential Drug List which would be based upon the needs of the state. However, the result was in favour of pharmacists.
3. There were significant differences at the level (0.01) between the participants (physicians and nurses) in agreeing that Kuwait should establish an Essential Drug List which would be based upon the needs of the state. However, the result was in favour of physicians.

**Table 4.33 Results from the use of the Scheffe Method, and the significant differences between the means of interviewees (pharmacists, physicians and nurses) on question 10 of the questionnaire.**

| *Question No* | *Profession* | *Pharmacist* | *Physician* | *Nurse* |
|---|---|---|---|---|
| *10* | *Pharmacist M(1.78)* | -- | | |
| | *Physician M(1.79)* | *0.01* | -- | |
| | *Nurse M(0.36)* | *1.42* | *1.43* | -- |

*Scheffe Range = 0.818*

This table shows that:

1. There were no significant differences between the participants (pharmacists and physicians) in thought that the development of the pharmaceutical industries in Kuwait ought to improve.
2. There were significant differences at the level (0.05) between the participants (pharmacists and nurses) in agreeing that development of the pharmaceutical industries in Kuwait should substantially improve. However pharmacists' responses were closest to support the findings.
3. There were significant differences at the level (0.05) between the participants (physicians and nurses) in agreeing that development of the pharmaceutical industry in Kuwait should substantially improve. However physicians' responses were closest to support the findings.

**Table 4.34 Results from use of the Scheffe Method and the significant differences between the means of interviewees (pharmacists, physicians and nurses) on the total degree of the questionnaire.**

| *Question No* | *Profession* | *Pharmacist* | *Physician* | *Nurse* |
|---|---|---|---|---|
| *All Questions* | *Pharmacist M(2.77)* | -- | | |
| | *Physician M(2.76)* | *0.01* | -- | |
| | *Nurse M(1.61)* | *1.16* | *1.15* | -- |

*Scheffe Range = 0.744*

This table shows that:

1. There were no significant differences between the participants (pharmacists and physicians) in the responses to the questionnaire as a whole.
2. There were significant differences at the level (0.05) between the participants (pharmacists and nurses) in the responses to the questionnaire as a whole. However, the result was in favour of the pharmacists.
3. There were significant differences at the level (0.05) between the participants (physicians and nurses) in the responses to the questionnaire as a whole. However, the result was in favour of physicians.

**Results of the fifth hypothesis**

This hypothesis indicated that there is no statistically significant difference between the sample responses to the questions in the questionnaire due to the different workplaces of participants (hospitals, health administrations, drug companies, health clinics, research center and pharmaceutical faculty).

To validate this hypothesis, the One Way Analysis of Variance method was used to examine the degrees of the workplaces of participants to the questions of the questionnaire. The result can be observed in the table below (page 143, 144 and 155).

**Table 4.35 Results of the use of the One Way Analysis of Variance method to examine the degrees of the participants working in different health places**

| *Ques No* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *1.* | *Between Groups* | *38.30* | *5* | *7.66* | *2.11* | *No significance* |
| | *Within Groups (error)* | *417.45* | *115* | *3.63* | | |
| | *Total* | *455.75* | *120* | | | |
| *2.* | *Between Groups* | *17.70* | *5* | *3.54* | *1.60* | *No significance* |
| | *Within Groups (error)* | *254.15* | *115* | *2.21* | | |
| | *Total* | *271.85* | *120* | | | |
| *3.* | *Between Groups* | *46.00* | *5* | *9.20* | *2.00* | *No significance* |
| | *Within Groups (error)* | *529.00* | *115* | *4.60* | | |
| | *Total* | *575.00* | *120* | | | |
| *4.* | *Between Groups* | *24.20* | *5* | *4.84* | *2.01* | *No significance* |
| | *Within Groups (error)* | *277.15* | *115* | *2.41* | | |
| | *Total* | *301.35* | *120* | | | |

**Follow Table 4.35 Results of the use of the One Way Analysis of Variance method to examine the degrees of the participants working in different health places**

| *No. 0f Ques.* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *5.* | *Between Groups* | *16.10* | *5* | *3.22* | *1.73* | *No significance* |
| | *Within Groups (error)* | *213.90* | *115* | *1.86* | | |
| | *Total* | *230.00* | *120* | | | |
| *6.* | *Between Groups* | *19.90* | *5* | *3.98* | *2.30* | *No significance* |
| | *Within Groups (error)* | *198.95* | *115* | *1.73* | | |
| | *Total* | *218.85* | *120* | | | |
| *7.* | *Between Groups* | *13.05* | *5* | *2.61* | *2.16* | *No significance* |
| | *Within Groups (error)* | *139.15* | *115* | *1.21* | | |
| | *Total* | *152.20* | *120* | | | |
| *8.* | *Between Groups* | *16.15* | *5* | *3.23* | *2.21* | *No significance* |
| | *Within Groups (error)* | *167.90* | *115* | *1.46* | | |
| | *Total* | *184.05* | *120* | | | |
| *9.* | *Between Groups* | *18.10* | *5* | *3.62* | *1.31* | *No significance* |
| | *Within Groups (error)* | *317.40* | *115* | *2.76* | | |
| | *Total* | *335.50* | *120* | | | |

**Follow Table 4.35 Results of the use of the One Way Analysis of Variance method to examine the degrees of the participants working in different health places**

| *No. 0f Ques.* | *Source of Variation* | *Sum of squares* | *Degrees of Freedom* | *Average Squares* | *F Value* | *Level of significance* |
|---|---|---|---|---|---|---|
| *10.* | *Between Groups* | *16.50* | *5* | *3.30* | *2.31* | *No significance* |
| | *Within Groups (error)* | *164.45* | *115* | *1.43* | | |
| | *Total* | *180.95* | *120* | | | |
| *11.* | *Between Groups* | *20.25* | *5* | *4.05* | *1.66* | *No significance* |
| | *Within Groups (error)* | *280.60* | *115* | *2.44* | | |
| | *Total* | *300.85* | *120* | | | |
| *All Ques.* | *Between Groups* | *15.50* | *5* | *3.10* | *2.20* | *No significance* |
| | *Within Groups (error)* | *162.15* | *115* | *1.41* | | |
| | *Total* | *177.65* | *120* | | | |

**F(5,115,0.05)= 2.44*

It can be seen from this table that there is no significant difference between the responses of the research sample to the questions in the questionnaire or on its total degrees.

4.7.2 Qualitative Analysis

In this analysis, the hypothesis provided that there were no statistically significant differences between the research samples in their responses regarding the reasons for their responses to the questions in the interview.

To validate this hypothesis, the frequency of responses giving reasons were calculated, and this was then given as a percentage. In addition, the Chi-Square Test was used to identify the significance of the differences between the frequencies of responses of research samples to the reasons for answering the interview questions. The result is observed in the table below.

**Table 4.36 Results of the use of the Chi-Square Test ($x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 1 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *1* | *A* | *21*<br>*17.4* | *1.93* | *No significance ** |
| | *B* | *23*<br>*19.0* | | |
| | *C* | *30*<br>*24.8* | | |
| | *D* | *24*<br>*19.8* | | |
| | *E* | *23*<br>*19.0* | | |

*

$x^2(4.0.05) = 9.488$

The responses of the interviewees to question 1 included:

- Response (A): To develop and improve the health care system and reregulate the legislations and regulations of the pharmaceutical sector.
- Response (B): To ensure access to safe, effective and quality drugs.
- Response (C): To reduce the issues related to drugs and setting up necessary health organizations (for example, quality assurance department, Essential Drug List and pharmacovigilance center).

- Response (D): To apply better control over traded drugs, improve the rational use of drugs and ensure availability of drugs in the country with good cost-effectiveness.
- Response (E): To provide guidelines and protocol for the health professionals.

It can be seen from the table above that there were no significant differences between the mentioned responses of research sample to question1 in the interview. This means that the listed responses occurred by chance. For this reason, the researcher believes that a lack of an NDP in Kuwait impacted on participants' responses and on their understanding and knowledge of the importance of this policy.

**Table 4.37 Results of the use of the Chi-Square Test ($x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 2 of the interview.**

| *No. 0f Ques.* | *Responses* | *Frequency and Percent* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *2* | *A* | *23*<br>*19.0* | *35.24* | *0.01 ** |
| | *B* | *29*<br>*24.0* | | |
| | *C* | *19*<br>*15.7* | | |
| | *D* | *45*<br>*37.2* | | |
| | *E* | *5*<br>*4.1* | | |

$*x^2(4.0.01) = 13.277$

In addition to the information above, the responses of the interviewees to the Question 2 included:

- Response (A): The health care system can be improved by increasing control and monitoring over drugs and strengthening the penalties.
- Response (B): The health care system can be improved by developing the training programs for health professionals (pharmacists, physicians and nurses) and by improving their health education level.
- Response (C): The health care system can be improved by providing software programs and electronic link system between health places of the KMOH.
- Response (D): The health care system can be improved by establishing further research centers, pharmacovigilance center, quality assurance departments, Essential Drug List and a NDP in Kuwait.
- Response (E): The health care system cannot be developed because of the lack of guidelines which regulate the health sector and the absence of decisions to improve the health system.

This table shows that there were significant differences at level (0.01) between the mentioned responses of the research sample to question 2 with highest frequency emphasized by response D as it involved the largest number of participants (N=45).

**Table 4.38 Results of the use of the Chi-Square Test ($x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 3 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *3* | *A* | *15*<br>*13.6* | *15.10* | *0.05** |
| | *B* | *12*<br>*9.9* | | |
| | *C* | *12*<br>*9.9* | | |
| | *D* | *19*<br>*15.7* | | |
| | *E* | *8*<br>*6.6* | | |
| | *F* | *24*<br>*19.8* | | |
| | *G* | *9*<br>*7.4* | | |
| | *H* | *12*<br>*9.9* | | |

$*x^2(7, 0.05) = 14.067$

The responses of the interviewees to question 3 included:

- Response (A): Absence of knowledge on the economics related to the system from the MOH regulators such as drug cost effectiveness and supply management.
- Response (B): Delays in the decision-making process from KMOH regulators and lack of centralization.
- Response (C): Need for more hospitals and medical beds and weakness in control over the traded drugs in the private market (for example, the increase in counterfeit and unlicensed drugs).
- Response (D): Lack of sufficient training programs and conferences for health professionals.

- Response (E): The need to have more research centers in the state because there is only one research center (Dasman Diabetes Institute).
- Response (F): Absence of cooperation between KMOH administrations, hospitals and health clinics due to lack of an IT link system.
- Response (G): The health care system in Kuwait is well-structured and there are no clear issues.
- Response (H): The question was not considered applicable.

This table shows that there were significant differences at level (0.05) between the mentioned responses of the research sample to question 3 with highest frequency emphasized by response F as it included the largest number of participants (N=24).

**Table 4.39 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 4 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *4* | *A* | *36*<br>*29.8* | *33.29* | *0.01** |
| | *B* | *27*<br>*22.3* | | |
| | *C* | *13*<br>*10.7* | | |
| | *D* | *20*<br>*16.5* | | |
| | *E* | *11*<br>*9.0* | | |
| | *F* | *14*<br>*11.6* | | |

$*x^2(5, 0.01) = 15.086$

The responses of the interviewees to question 4 included:

- Response (A): There is enough control over drug registration and over secondary control after licensing.
- Response (B): There is sufficient inspection and monitoring over public and private pharmacies, drug stores and pharmaceutical companies.
- Response (C): There is insufficient control over the private market due to the presence of counterfeit and unregistered drugs.
- Response (D): There is not enough control over the private sector, with the dispensing of prescribed drugs without prescription (for example, antibiotics).
- Response (E): The issue of not having enough control because of the lack of a pharmacovigilance center in Kuwait.
- Response (F): Weakness of penalties for the irregularities is the main reason for the absence of sufficient control over the pharmaceutical sector.

This table shows that there were significant differences at level (0.01) between the mentioned responses of the research sample to question 4 with highest frequency given for response A, as it included the largest number of participants (N=36).

**Table 4.40 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 5 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *5* | *A* | *38*<br>*31.4* | *10.21* | *0.05 ** |
| | *B* | *21*<br>*17.4* | | |
| | *C* | *40*<br>*33.1* | | |
| | *D* | *22*<br>*18.2* | | |

* $x^2(3, \quad 0.05) = 7.805$

The responses of the interviewees to question 5 included:

- Response (A): There is a lack of training programs (for example, in clinical, ethical, communication and medical skills programs) for health professionals, specifically for newly-graduated staff.
- Response (B): The pharmacists training programs are insufficient and there is an absence of any training programs for the inspectors and staff of the pharmaceutical administrations in the public sector (drug control, central medical store and drug inspection administrations).
- Response (C): There were enough and appropriate training programs for health professionals due to the existence of a one year training rotation course for the newly-recruited staff.
- Response (D): There are not enough training programs for physicians and nurses in the public sector, in addition, there is an absence of medical conferences, seminars, lectures and workshops for nurses.

This table shows that there were significant differences at level (0.05) between the mentioned responses of research sample to question 5 with highest frequency given to response C because it included the largest number of participants (N=40). However, the total number of interviewees who answered that the training programs in Kuwait are insufficient were 81, and their answers were distributed across the other responses (A, B and D).

**Table 4.41 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 6 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *6* | *A* | *43*<br>*35.5* | *19.13* | *0.01** |
| | *B* | *22*<br>*18.2* | | |
| | *C* | *41*<br>*33.9* | | |
| | *D* | *15*<br>*12.4* | | |

$*x^2(3, \quad 0.01) = 11.345$

The responses of the interviewees to question 6 included:

- Response (A): The price range of medication in the private sector is not acceptable when compared to the prices in other Gulf countries (for example, KSA), where the drugs prices in Kuwait are three times more expensive.
- Response (B): The price range of medication in the private sector is not acceptable as the Pricing Department of the Drug and Food Control Administration is not qualified and strict enough in dealing with the private drugs prices and specifically the prices of generic drugs.

Response (C): The price range of medication in the private sector is acceptable even when compared to the prices in KSA because the drugs prices are related to a number of factors such as the population of KSA is the largest in the Gulf area so ordering in bulk makes it cheaper than Kuwait. In addition, there is an absence of a pharmaceutical industry in Kuwait whereas affected negatively in increasing the needs for the imported drugs and cause an increase in the price range of the drugs.

- Response (D): The answer was not applicable due to the interviewees not knowing information about the price range of medication in the private sector.

This table shows that there were significant differences at level (0.01) between the mentioned responses of research sample to question 6 with highest frequency given to response A, because it included the largest number of participants (N=43).

**Table 4.42 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 7 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *7* | *A* | *29*<br>*24.0* | *2.21* | *No significance ** |
| | *B* | *37*<br>*20.6* | | |
| | *C* | *26*<br>*21.5* | | |
| | *D* | *29*<br>*24.0* | | |

$*x^2(3, \quad 0.05) = 7.805$

The responses of the interviewees to question 7 included:

- Response (A): There were no issues with access to quality, safe and effective drugs because the available drugs in the public sector are of the best quality and the medications are available for free for the citizens and residents in the State.
- Response (B): There were no issues with access to quality, safe and effective drugs because all the drugs in the private market are under the

control of the KMOH, where drugs should be registered and licensed by the Drug and Food Control Administration before they are sold in the market.

- Response (C): There are issues in this respect because there is not enough control and there is weakness in the inspection of drugs sales in the private sector, specifically in the sale of non-prescription drugs.
- Response (D): The main issues related to this aspect are the lack of a pharmacovigilance center and drug information center in Kuwait.

It can be seen from the table above that there are no significant differences between the mentioned responses of the research sample to question 7 in the interview, which means that the listed responses were the result of chance.

**Table 4.43 Results of the use of the Chi-Square Test ( $x^2$) to identify the**

| *No. Of Ques.* | *Responses* | *Frequency and Percent* | *Chai square* $x^2$ | *Level of Significant* |
|---|---|---|---|---|
| *8* | *A* | *56*<br>*46.3* | *63.90* | *0.01** |
| | *B* | *26*<br>*21.5* | | |
| | *C* | *23*<br>*19.0* | | |
| | *D* | *6* | | |

**significant differences between the frequency of responses of research samples to the reasons for answering Question 8 of the interview.**

| | | | | |
|---|---|---|---|---|
| | | 5.0 | | |
| | E | 10<br>8.3 | | |

*$x^2$ (4,0-01)=13,277

The responses of the interviewees to question 8 included:

- Response (A): There is a problem with irrational use of prescription drugs in Kuwait, specifically usage of antibiotics, sexual products and hormones.
- Response (B): There is an increase in the irrational use of drugs in the country due to the issue of self-medication among the public.
- Response (C): There is issue with irrational use of drugs due to weak health education of patients and specifically the elderly, as well as the low education of some physicians in prescribing inappropriate medications to patients.
- Response (D): The answers were not applicable because the interviewees did not have enough information about the irrational use of drugs in Kuwait and they could not take a decision in this question.
- Response (E): There is no irrational use of drugs in both the public and private sector in Kuwait.

This table shows that there are significant differences at level (0.01) between the mentioned responses of the research sample to question 8 with the highest frequency given from response A, because it included the largest number of participants (N=56).

**Table 4.44 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 9 of the interview.**

$*x^2(4, \quad 0.01) = 13.277$

| Ques No | Responses | Frequency and Percentage | Chi square $x^2$ | Level of Significance |
|---|---|---|---|---|
| 9 | A | 24<br>19.8 | 40.14 | 0.01* |
| | B | 49<br>40.5 | | |
| | C | 20<br>16.5 | | |
| | D | 22<br>18.2 | | |
| | E | 6<br>5.0 | | |

The responses of the interviewees to question 9 included:

- Response (A): Kuwait should establish an Essential Drug List based upon the appropriate needs of the country for the medications to ensure availability and affordability of the main drugs.
- Response (B): The Essential Drug List is very important to the State and it would lead to savings to the national budget.
- Response (C): The Essential Drug List is important for determining the appropriate needs of drugs for the long term for both the public and private sector.
- Response (D): The Essential Drug List would help to reduce any costs associated with adverse reactions and ensure drug effectiveness.
- Response (E): The question is not applicable because the interviewees do not know enough about it.
- Response (F): There is no reason to have an Essential Drug List in Kuwait.

This table shows that there were significant differences at level (0.01) between the mentioned responses of the research sample to question 9 with highest frequency given by response B, because it included the largest number of participants (N=49).

**Table 4.45 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 10 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *10* | *A* | *24*<br>*19.8* | *40.14* | *0.01 ** |
| | *B* | *49*<br>*40.5* | | |
| | *C* | *20*<br>*16.5* | | |
| | *D* | *22*<br>*18.2* | | |
| | *E* | *6*<br>*5.0* | | |

$*x^2(4, \quad 0.01) = 13.277$

The responses of the interviewees to question 10 included:

- Response (A): The presence of a pharmaceutical industry would secure the country's medicines resources and reduce the monopoly of international drugs companies.
- Response (B): The pharmaceutical industries would help availability of drugs during emergencies and wars.
- Response (C): It would increase and improve the national sources of income and improve the pharmaceutical technologies.
- Response (D): There is no benefit to having a pharmaceutical industry in Kuwait because it will cost more than purchasing imported drugs and specifically generic drugs.
- Response (E): In Kuwait there is a lack of certain factors that would lead to success in drug production, such as a high level of technologies, quality trained staff and research centers.

**Table 4.46 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 11 of the interview.**

| *Ques No.* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *11* | *A* | *13*<br>*10.7* | *137.33* | *0.01 ** |
| | *B* | *101*<br>*8.5* | | |
| | *C* | *7*<br>*5.8* | | |

*$*x^2$ (1,0.01)=9.210*

This table shows that there were significant differences at level (0.01) between the mentioned responses of the research sample to question10 with highest frequency given from response C, because it included the largest number of participants (N=47).

The responses of the interviewees to question 11 included:

- Response (A): It is a suitable time to establish a NDP in Kuwait and the KMOH had all the necessary factors and the base structure to work on this action plan.
- Response (B): The KMOH should start working on the establishment of a NDP but first it should provide and improve appropriate factors to complete this action successfully.
- Response (C): The KMOH does not have sufficient capacity, is unable to take the decisions and cannot successfully produce a NDP in the country at this current time.

This table shows that there were significant differences at level (0.01) between the mentioned responses of the research sample to question 11 with highest frequency given from response B because it included the largest number of participants (N=101).

**Table 4.47 Results of the use of the Chi-Square Test ( $x^2$) to identify the significant differences between the frequency of responses of research samples to the reasons for answering Question 12 of the interview.**

| *Ques No* | *Responses* | *Frequency and Percentage* | *Chi square* $x^2$ | *Level of Significance* |
|---|---|---|---|---|
| *12* | *A* | *17*<br>*14.0* | *28.38* | *0.01 ** |
| | *B* | *25*<br>*20.7* | | |
| | *C* | *12*<br>*9.9* | | |
| | *D* | *46*<br>*38.0* | | |
| | *E* | *21*<br>*17.4* | | |

**$x^2$ (4,0.01)=13.272*

The responses of the interviewees to question 12 included:

- Response (A): It would develop and strengthen the present guidelines for the legislations and regulations related to drugs.
- Response (B): It can help to improve the level of the pharmaceutical sector, such as drug registration, inspection, supply management, procurement, dispensing, control and monitoring and ensure availability of safe and effect drugs in the State.

- Response (C): It would support the establishment and existence of necessary health departments and organizations such as quality assurance, pharmaovigilance and research centers.
- Response (D): It could improve the health care system by solving many issues such as the lack of an Essential Drug List, IT link system and training programs, as well as reduce the spread of counterfeit drugs in the private market and increase the rational use of drugs.
- Response (E): It would develop the cooperation between the health organizations, administrations, hospitals, associations and university through a discussion forum to define goals and objectives of the health care system and set priorities.

This table shows that there were significant differences at level (0.01) between the mentioned responses of the research sample to question 12 with highest frequency given from response D because it included the largest number of participants (N=46).

### 4.8 Limitations of the study

During the undertaking of the study the researcher was faced with some limitations and problems. First, the researcher wanted to apply a different method of interview, namely one with a focus on discussions between participants. However, it was difficult to arrange a meeting between the groups of participants due to time restrictions. Second, participants (pharmacists) were the largest sample size which potentially indicates their interest in participating. This meant there was a smaller sample size of other participants such as physicians and nurses as it was hard to access them and also because of the time pressure which prevented them from taking part in the study. In fact, some physicians were extremely disinterested and unwilling to participate, to the point that they expressed it verbally. In addition, a lack of an IT-link system between health areas of KMOH created more work and consumed more time for the researcher at the data collection stage.

### 4.9 Strength of the study

Lack of previous studies, finding sufficient research resources and statistics related to the development of a NDP in Kuwait were some of the difficulties but the researcher found in these difficulties a unique challenge as it was necessary to take action to establish the initial ground for development of a NDP in the State. In addition, the study combined quantitative and qualitative approaches in order to improve its robustness and to facilitate exploration through the opinions of participants. Moreover, the validity and reliability of the questionnaire increased when these two different methods were used (quantitative and qualitative methods).

# Chapter 5.0: The Pharmaceutical Sector in State of Kuwait

The pharmaceutical sector is one of the most important areas for the Health Care System in Kuwait. It includes all the pharmaceutical services in the public and private sectors in the country, also it ensures the access, affordability and availability of the drugs for the patients and is responsible for ensuring the quality, safety and efficiency of the medicines which are used.

It is proposed that the establishment of a Kuwaiti NDP should support an increase in the development and improvement of the pharmaceutical sector by introducing, organizing, operating and reviewing the policies which would be introduced and could be built upon in the future. In addition such developments would be expected to lead to reregulation of the pharmaceutical legislations and regulations and work towards updating to keep pace with the requirements and needs for the future.

It is proposed that the major outcome and analysed data from the structured interviews (presented in Chapter 4) provides an understanding of the current position of the pharmaceutical sector in Kuwait. In this Chapter the present pharmaceutical services in the public and private sectors in Kuwait are further identified, studied and discussed, in order to understand the nature of the pharmaceutical operation in Kuwait, and how legislations and regulations are used. Also the issues and requirements of this sector are identified and procedures are discussed with proposals and solutions which could help accommodate the establishment of a NDP.

## 5.1 The Public Sector

The public pharmaceutical sector in the State of Kuwait includes all the pharmaceutical administrations of the Kuwaiti Ministry of Health (KMOH). These administrations are divided into 4 main areas which are the:

1. Pharmaceutical Services Administration.

2. Drug and Food Control Administration.

3. Central Medical Store Administration.

4. Drug Inspection Administration.

The four administration units are managed through the Assistant Undersecretary of Drugs and Medical Supplies Affairs in KMOH (Dr. Omar, the third supervisor). Each of the administrations has their own general Director, administrative structure, and health professional staff and is responsible for regulating and developing their own work and they seek to ensure appropriate services to the consumers and improvements in the health care system under the supervision of the Ministry of Health. See Figure 5.1 (KMOH, 2011 a) (Alali, 2011).


**Figure 5.1.The structure of pharmaceutical sector for the KMOH (KMOH, 2011 a)**

### 5.1.1 Pharmaceutical Services Administration.

In the 1980's the KMOH wanted to develop further the pharmaceutical services in line with the health situation in the country, and it was decided to established the

pharmaceutical services administration in 1985 (Ministerial Decree.166, which was amended by the Ministerial Decree.67 and 151 in the year 1986). (KMOH, 2011 b)

The Pharmaceutical Services Administration is responsible for many duties, such as:

1. Participation in the development of the general plan on the regulation of pharmaceutical services and in the follow-up and implementation of these regulations after adoption.

2. Carrying out all the work and tasks related to the provision of pharmaceutical services in accordance with the general plan of the MOH.

3. Supervising the preparation of pharmaceutical patient leaflets and moderating periodically and developing services in coordination with the concerned authorities.

4. Coordination with regional and international institutions in the field of pharmaceutical services.

5. Coordination and technical supervision of the pharmacists in the public hospitals, health clinics and health centers.

6. Preparing annual reports on the activities of pharmaceutical services in the health areas, hospitals and health centers.

7. Preparing the annual needs of health professionals and the necessary equipment for the pharmaceutical services in coordination with the concerned authorities in this field.

8. Regulating and monitoring the pharmaceutical services in all Governmental hospitals and health clinics in the State of Kuwait, which covers 6 provinces, and it’s responsible for the work of pharmacists and technicians and for their training, developing, evaluation and distribution of medicines and devices to public pharmacies. It is the largest administration of the MOH that deals with patients. See Figure 5.2. (KMOH, 2011 c)

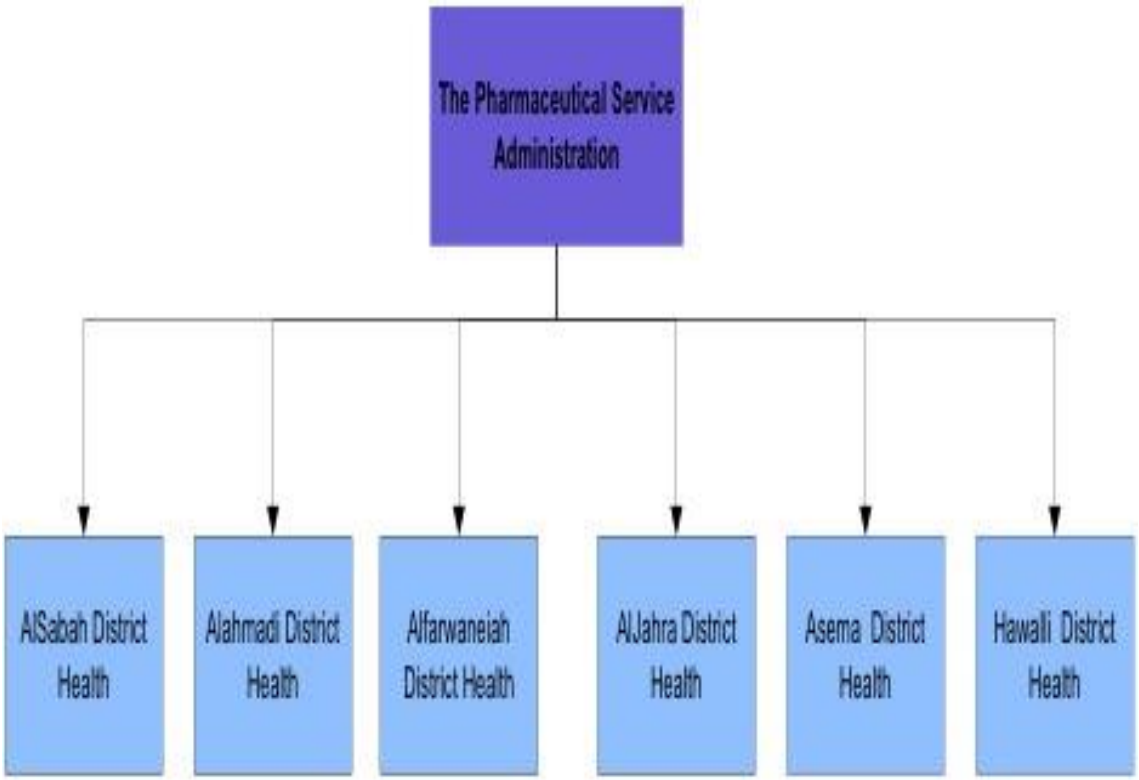


**Figure 5.2 Organization Structure of Pharmaceutical Services Administration (KMOH, 2011 c) (MSc, 2011)**

- The structure of the Pharmaceutical Services Administration:

This administration consists of two supervisions, the:

1. Planning and training supervision.
2. Coordination and follow-up supervision.

As was mentioned above, this administration is responsible for introducing training courses for the pharmacists and technicians. But there is only one training program for the new pharmacists working in KMOH. The period of this training course is 1 year and includes: working 2 months in a Public Health Center, 6 months in Public General Hospital and 4 months in a Private Hospital. Through this rotation training course the pharmacist will work in many units to identify and learn the work in a

central pharmacy unit, medicine manufacturing unit, intravenous nutrition unit, unit of drug and mental effects, emergency unit, outpatient unit and medical storage unit.

After completion of this training course, the Administration distributes the pharmacists to the pharmacies which belong to the MOH. But after this training there is no any training course to update, improve and evaluate the pharmacist's scientific or practical level. (KMOH, 2014 a)

#### 5.1.1.1 The Review of the Pharmaceutical Services Administration for this Study

The Administration was visited during the PhD program (during the structured interviews and informal visits) discussions were undertaken with the staff at a number of levels (Further details of these discussions and number of staff involved can be found in chapter 4, page 90 - 94); From these studies, it was found that there were a number of concerns in the working system, and these included:

1. The lack of further training programs for the pharmacists and technicians.
2. Absence of updating courses and training studies for the senior staff.
3. The regrading system for pharmacists is generally not based on capability, but depends on the number of years in the workplace.
4. The shortage of access to internal and external professional conferences and symposia to which health professionals can attend and in some cases present at.

It was suggested in the structured interviews (in Chapter4) that the KMOH should be resolving these problems which it was felt would improve the professionalism of the Health Services and reflect positively in the health care system and with patients and this development should be introduced into an established NDP in the State.

### 5.1.2 Drug and Food Control Administration

The KMOH established the Drug and Food Control Administration in 1990, according to the Ministerial Decree.8.3 (KMOH, 2011 d). The reason for establishing this Administration was because it was considered very highly important as the main unit for controlling legislation in the pharmaceutical sector. In this respect it is responsible for many areas related to the quality and delivery of medicines, available to the population, and its function includes:

1. Responsibility for the registration of herbal and pharmaceuticals, cosmetic products, veterinary drugs, unclassified and medical devices products and food supplement products which are entering the country and control according to the Kuwaiti MOH rules and conditions.
2. Responsibility for the licensing of pharmaceutical products the other health products and for regulating their release into the pharmaceutical areas.
3. To carry out studies and develop statistics for the registered products and to classify them into defined categories.
4. To insure the co-operation with all local and international agencies which are concerned concern with the importation and distribution of medicines in Kuwait.
5. To ensure efficient medicines processing and drug control.
6. To ensure that all the legislations and pharmaceutical guidelines and controls are adhered to which confirm the quality and safety of the medicines and health products.
7. Responsibility for the registration of the drug companies in conducting business in the pharmaceutical field.
8. To provide guarantees that all imported and exported drugs are under GMP conditions before releasing them to the market.
9. Controls over the price of the drugs in the private market.

From examination of the information above it can be proposed that a successful establishment of a NDP is likely to depend to a large extent on the efficiency of the Drug and Food Control Administration, and there is a suggestion for the KMOH to

support the Administration and help in establishing a NDP, and the KMOH should develop and improve this Administration, solve any issue in its system and contribute to improving the level of health professional staff to ensure the continuity of the success of the work on developing the NDP in Kuwait (KMOH, 2015 b).

The organization structures of the Drug and Food Control Administration, consists of two main supervision units and three individual Departments:

1. Registration Supervision.

2. Laboratories Supervision.

3. Drug Pricing Department.

4. Drug Release Department in Kuwait International Airport.

5. Quality Assurance Department. (KMOH, 2015 b)

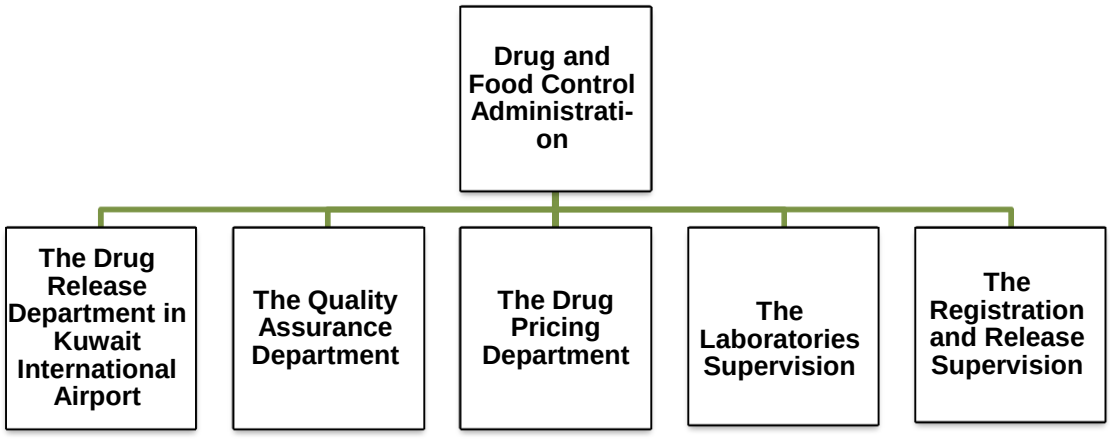


**Figure 5.3 Organization Structure of Drug and Food Control Administration (KMOH, 2015 b)**

5.1.2.1 The Registration and Release Supervision

This Supervision is concerned with the registration, licensing and releasing of the pharmaceutical, herbal, veterinary, cosmetics, food supplements and non-classified medicines and products.

**-** The objectives of Drug/Product registrations and release are to:

1. Ensure that all medicines and pharmaceutical products which imported or manufactured in the country are evaluated and registered by Drug and Food Control Administration.

2. Ensure the quality, safety and efficacy of all the imported/ used drugs.

3. Obtain the benefit from the particular product accompanied by the appropriate professional advice.

4. Ensure that all the drug companies are registered and licensed under the rules of the Administration and to regulate and follow them through the process of dispensing to the patient. (KMOH, 2015 c)

- The advantages which could be developed from Drug Registrations are: (From direct experience of working in this area during 7 years and from observation and discussion with a supervisor of this area during the structured interviews):

1. Some of the revenue from Registration Fees could be used by the MOH to develop this Department.

2. As the reporting of adverse drug reactions is not commonly carried out it should be further supported and promoted.

3. To ensure that all the Branded and Generics Medicines meet quality standards and are under the required control.

- Types of registrations, which are under the Drug and Food Control Administration:

1. Pharmaceutical Products (capsules, injections, serums and tablets).
2. Herbal Products.
3. Food Supplement Registration.
4. Cosmetic Products.
5. Unclassified and Medical Devices Registration.
6. Veterinary Products.
7. Pharmaceutical Companies and Agencies Registration.
8. Drug Stores and Warehouses Registration. (KMOH, 2015 c)

- This is one area which may benefit from an examination of its operation. For instance to register a new product with the Kuwaiti Drug Control Department could take three months for each application, if all the requirements are submitted appropriately. This could be considered a convenient approval time at three months, when compared with a number of other countries. For instance in: Algeria (registration time=7 months), Nigeria (registration time=4 months) and Uruguay (registration time=5 months). But in other developing countries the registration time is shorter, such as in Costa Rica the registration's time is six weeks. This is one area where the KMOH could examine the operation to ensure that the assessment of the drug registration period is as efficient as it could be and reduce it if possible in order to provide faster access of drugs to the public. (Kaplan and Laing, 2003).

In addition the license certificate lasts for 2 years and can be renewed. It is a requirement that all the drugs/medicines to include: imported - exported drugs stored and sold medicines and locally produced medicines should be registered before it reaches the consumer or patient.

The Registration and Release Supervision consists of eight departments to include:

- Pharmaceutical registration department.

- Herbal registration department.

- Veterinary registration department.

- Unclassified and medical devices registration department.

- Invoice release department.

- Food supplements registration department.

- Cosmetics registration department.

- Training department.

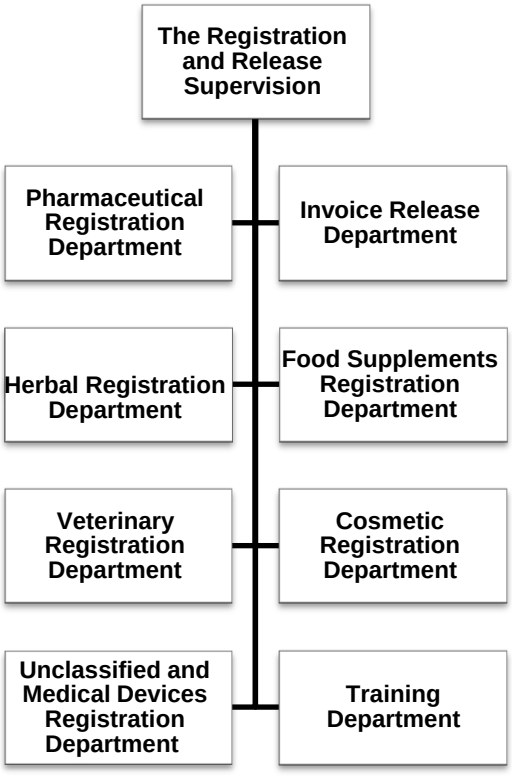


**Figure 5.4.The Organization Structure of the Registration and Release Supervision (KMOH, 2015 c)**

a) Pharmaceutical Registration Department:

which specializes in:

1. Registration of imported and local manufactured medicines according to the registration rules.
2. Giving the first and final release for imported medicines after ensuring the accompanying paperwork, invoices and checks that the items are registered.
3. Taking control of the entire drug invoices and medicines parcels and ensuring that the paperwork obeys the regulatory rules.
4. Giving licenses for the approved registered drugs.
5. Giving licenses for the pharmaceutical companies and agencies.
6. Giving licenses for the drug/medicines storage and warehousing.

In order to receive the licenses the Drug Companies should follow the rules and conditions of the Drug and Food Control Administration, which are clearly stated below.

a1) Requirements for registration of pharmaceutical products, includes:

1. Provision of samples including: packaging, patient leaflet in Arabic or English language and the written information on the medicine e.g. storage conditions, the brand or generic name, active ingredient and shelf life.

2. Certificate of Pharmaceutical Products (CPP), and it should be original and legalized from the Kuwaiti Embassy in the country of origin.

3. Original and legalized Good Manufacture Practice (GMP) Certificate.

4. Any clinical studies for the pharmaceutical product under registration.

5. Stability studies (long term study and accelerated study).

6. Provision of Bioequivalent study (only for the generic products).

7. Pricing certificate for the pharmaceutical product under registration.

8. Drug Analysis Certificate.

9. Certificate shows if the product was registered in other countries.

b). Herbal Registration Department:

It specializes in:

1. Registration of the imported and local manufactured herbal products according to the registration rules.
2. Giving the first and final releases for the imported herbal products after insuring the invoices and checking that the items were registered.
3. Checking of the entire herbal product invoices and herbal parcels and insure that they are under the rules.
4. Provision of licensing for the approved registered herbal products.

c). Veterinary Registration Department:

It is specializes in:

1. Registration the imported and local manufactured veterinary drugs according to the registration rules.
2. Giving the first and final releases for the imported veterinary drugs after insuring the invoices and checking that the items were registered.
3. Making control for the entire veterinary drugs invoices and veterinary drugs parcels and insure that it was under the rules.
4. Giving licensing for the approved registered veterinary drugs.

c1) - There is a list of requirements for registering a veterinary company, such as:

1. Legalized and original manufacturing license.
2. Legalized and original letter of appointment issued by the mother (original) company.
3. Legalized and original GMP certificate.
4. The company profile.

c2) - There are list of basic requirements for registering a veterinary product for non-consumption animals (Pets, horses and birds), such as:

1. Finished product sample.

2. Legalized and original price certificate.

3. Legalized and original Free Sale Certificate or CPP.

4. Finished product specifications.

5. Certificate of Analysis Product (with the same batch number of the sample submitted).

c3) - The basic requirements for the registration of a veterinary product for human consumption animals are:

1. Finished product sample.

2. Legalized and original price certificate.

3. Legalized and original Free Sale Certificate or CPP.

4. Finished product specifications.

5. Certificate of Analysis Product (with the same batch number of the sample submitted).

6. Summary of product characteristics.

7. Source of supply of active ingredients.

8. List of countries where the product is registered with registration dates.

9. Raw material specifications.

10. Stability studies.

11. Clinical studies.

12. Toxicological and residue studies.

13. Certificate of drug residue and withdrawal period.

d). Unclassified and Medical Devices Registration Department:

It specializes in:

1. Registration the imported and local manufactured unclassified and medical devices products according to the registration rules.
2. Giving the first and final releases for the imported unclassified and medical devices products after insuring the invoices and checking that the items were registered.
3. Making control for the entire unclassified and medical devices products invoices and unclassified and medical devices products parcels and insure that it was under the rules.
4. Giving licensing for the approved registered unclassified and medical devices products.

e). Drug Release Department:

It specializes in:

1. Co-operating with Kuwait's marine, air and land ports, and regulates the coordination between them and the Drug Control Administration.
2. Monitoring all imported drugs, pharmaceuticals products, herbal, veterinary, medical devices, food supplement and cosmetic shipments and parcels, and matches finance to the imported products.
3. Supervising the re-export (rejection of) pharmaceutical products and food supplements which are not allowed to be used in the country.

e1) The Drug Release Department includes the following offices and sections to include the:

1. Release Office in Kuwait International Airport.
2. Release Office in AL Shuwaikh Port.
3. Land Customs office.
4. Kefan Post office.

f). Food Supplement Registration Department:

It specializes in:

1. Registration of imported and locally manufactured food supplements products according to the registration rules.
2. Giving the first and final releases for the imported food supplement products after ensuring the authenticity of invoices and the checking that the items were registered.
3. Control of the entire food supplement product invoices and food supplement parcels and insuring that they come under the rules.
4. Giving licensing for the approved registered food supplement products.
5. Researching and studying chronic diseases for different age groups and finding good solutions for these health issues.
6. Developing and carrying out training programs for health professionals to increase their efficiency in their work.

g). Cosmetic Registration Department:

It specializes in:

1. Registration of imported and locally manufactured cosmetic products according to the registration rules.
2. Giving the first and final release for the imported cosmetic products after insuring the invoices and checking that the items were registered.

3. Controlling of the entire cosmetic product invoices and cosmetic parcels and insuring that they are under the rules.
4. Giving licenses for the approved registered cosmetic products.

h). Training Department:

It specializes in:

1. Developing training programs and courses in drug control and drug registration for the health professionals in the administration.
2. Monitoring and regulating the visits of medical and pharmaceutical students to the administration.

All these points appear to be appropriate however during the fieldwork for this PhD research study, the basis and how these operations are carried out was investigated further. From this the main issues found in the Registration System were obtained through informal visits in this administration (in 2015) as well as the structured interviews with the staff (in 2014) (Further details of these visits, discussions and number of staff involved was discussed in chapter 4), However the main points were that:

1. The staff needs more training course and experience in the following:

A. Bioequivalence test study.

B. Stability Studies.

C. GMP training courses.

D. Clinical test studies.

The structured interviews which were carried out were conducted with four senior staff: the Assistant Under Secretary for Drug and Medical Supplies of the KMOH, Director and Supervisor of registration and release of drugs; and Head of the drug registration department of Drug and Food Control Administration, who were each

interviewed. The main points that they raised were that the staff needed more training programs in the aspects mentioned above. These comments were also backed up in the informal discussions with other staff in the same administration who also stated that there was a lack, generally of training programs for health professionals; but especially in the areas mentioned above. They also indicated that there should be programs of a practical nature in their field in order to increase their skills and reduce their work errors.

2. Another area which was mentioned and should be given priority is that there should be more computerization of the evaluation system as the present system does not easily support working and receiving applications manually.3. Prioritization of registration should be based on need.

4. There should be provision of a link system between all the departments to save effort and time.

5. There should be a listing of normal procedures and standards for registration of medical devices.

6. It is important to have a link system with the Central Medical Store.

7. That a drug index system for the Drug Control Administration would help the staff, health professionals and the agencies to know which are the registered drugs in Kuwait and this index should be update yearly.

8. A need to increase the co-operation with other local or international agencies.

9. To have an official web site for the Administration.

5.1.2.2 The Laboratories Supervision

This Supervision includes the following Departments:

1. Chemical Analysis Laboratory Department: which is concerned with the process of analysis of all imported drugs and pharmaceuticals to the State of Kuwait for both public and private sectors.

Chemical Analysis Laboratory Department which works on physicals tests (hardiness, dissolution and pH) and chemicals test (to include HPLC and UV). (KMOH, 2011 e) (MSc, 2011)

2. Pharmacology Laboratory Department: the functions of this Department are to conduct tests to ensure the safety of intravenous fluids and other similar medications, e.g. those which are used for diabetes, such as injecting insulin, for work using experimental animals and other tests for analyzing drugs.

Pharmacology Laboratory Department also carries out sterility and pyrogen tests. This Laboratory was renewed in 2011, and the methods changed from animal testing to HPLC and other tests to increase efficiency, reduce the cost and time consumed for animal care.

3. Microbiological Laboratory Department: which, is concerned with the process of laboratory experiments, which test stability, sterility, and includes an effectiveness test for the drugs, injections and medical devices. This Laboratory was renewed in 2011, and the methods also updated e.g. a dark room for the sample was built, and the air flow system was renewed and an enhanced disposal system for toxic waste was introduced. (KMOH, 2011 e) (MSc, 2011)

The issues were found in the laboratory system, when carrying out informal visits to this Administration in 2014-2015 (during PhD study). The informal discussions with the staff included mention of:

1. Insufficient numbers of Laboratory equipment for medicines analysis and assessment (e.g. dissolution baskets) which increases the time of the work and also lack of HPLC columns.

2. The need to expand the work areas in the Laboratories and to allow for the provision of space for writing up of the Laboratory results.
3. Overall there is the need for more equipment for pharmaceutical and biomedical analysis. (e.g. only one HPLC is currently available)
4. The needed to implement the latest GLP and SOPs procedures in the Laboratory.
5. Overall there should be assessments to try to reduce the overall time of analysis procedures.

5.1.2.3 The Drug Pricing Department

This Department operates directly under the control of the Assistant Undersecretary of Drugs and Medical Supply Affaires in Kuwaiti, which is managed by the Ministry of Health. Three pharmacists are working in this Department.

Its function is to:

1. Control and regulate the drug pricing for the private sector.

2. To make sure that the approved prices by the Ministry of Health are followed. (KMOH, 2011 f)

It is clear that these functions would become very important in the future development of a NDP. (KMOH, 2014 b)

During the studies it was proposed that when pricing the medicines, the Kuwaiti Government should take into account two important factors, 1) the balance between ensuring equal access and the make of the medicine affordable to the public, and at the same time still allowing drug companies to make profits which are essential for the return on their investment. The pharmaceutical companies argue that charging the current prices allows them to continue investing in research and development and producing the next generation of drugs (Moynihan et al., 2002). However, the National Governments and country collaborations e.g. Gulf

States (and particularly those with large cash reserves and population-size leverage) still have a major influence on the cost of medicines as they can put pressure on the companies as in the public sector they are responsible for the health of their residents and citizens. As a result particularly when countries come together they can, purchase medicines in bulk in their required amounts. Thus, the prices of drugs are generally determined as a compromise between both by what major governments are willing to pay, and what the companies believe is a overall product costs. For example, in the United Kingdom, the NHS is the country's largest buyer of pharmaceutical products and approaches companies to negotiate prices with them directly (House of Parliament, UK Government, 2010).

However this can be a confusing economic and healthcare web, and governments (Ministries of Health) have an important responsibility towards development of the drug sector. For instance, presently, the NHS was predicted to save £2.7 billion annually when it started buying generic versions of drugs that had come off patent (House of Parliament, UK Government, 2010). It can be suggested that is great news both for the government budgets and for the UK tax payer, but the question which can be asked is – 'what happens to the companies who may be losing out'? It may be suggested that often, it is the Generic Drug companies (along with the people of the country) who benefit. However the down side is that Generic Companies do not invest as heavily in R&D as do traditional Pharmaceutical Companies, meaning essentially, that generic companies do not develop new drugs – that task is still left to 'Big Pharma'. Ultimately, it can be said that if the R&D money dries up, fewer drugs may make it to market; which is especially concerning in certain areas such as where resistance is being felt; - given the rapid rise of antibiotic resistance and increasing autoimmunity and cancer incidence worldwide. Such problems are exacerbated at the present time by the fact that many developed economies are passing through a decade of stagnant growth (and even negative equity), driving steep budget cuts in health care and social services, and the lowering of drug prices (House of Parliament, UK Government, 2010).

However, faced with falling sales in certain areas, if 'Big Pharma' increases the price of new drugs then there becomes a vicious circle with no winner – such as

limited next-generation drugs able to cure modern ailments and known conditions more effectively – making them less available. Therefore, it is suggested that the governments have a responsibility to pharmaceutical companies and the wider economy (and nation's health) to ensure that fair prices are paid to the drug companies. As an example in the UK, separate government agencies decide upon which drugs they want, and how much they should cost, helping more objective, population-level statistical analyses to be made, and fairer prices reached, wherever possible – which is better for both sides in the long-term.

In this case, towards a productive end for both sides have tried to evade a trade war, the UK government and various pharmaceutical companies have entered into a voluntary agreement, called the Pharmaceutical Price Regulatory Scheme, which regulates the profits that companies can make from NHS sales (currently capped at nearly 30%); although in practice it is very difficult to determine which profits arose from the UK activities of very large companies, and creative accounting may mask any intended benefit. Within the agreement, pharmaceutical companies are also allowed to change the prices of drugs if new evidence concerning their use comes to light. However, as a sweetener for the government, the scheme also ensures that the price of each drug falls by 5% each year of continual use (House of Parliament, UK Government, 2010). Through such schemes, the public and private sectors might work together better for the benefit of taxpayers and patients. Finally, central to most successful drug purchases (and negotiations) are metrics of value-based pricing; i.e. what the particular drug is worth to that population at the time. In addition, recently, the new President of the USA (2016), suggested that big pharmaceutical companies would be made more accountable to the patients and public, stating that drug prices should be reduced to affordable levels (Landers, 2017).

Drug pricing however raises many ethical issues, as discussed (Green, 2008). Chief amongst these is the provision of drugs to the developing world. Classically,

pharmaceutical companies were not interested in selling drugs cheaply to less-developed nations as it did little to help their market capitalization. But this lead to deteriorating health conditions, epidemics and increased morbidity that could have been avoided for millions of people. The 'blind eye' turned by Big Pharma to the developing world over the last century can be said to be, 'amongst the greatest crimes for humanity'. In the last few years, however, major drug companies have thankfully begun selling drugs to low-income economies at reduced rates (mostly due to activist pressure and public opinion going against them), helping the drugs enter the healthcare systems where they are most needed (Gottlieb, 2000).

Overall unfortunately however, and perhaps unsurprisingly, the pharmaceutical industry is not remarkably transparent, and it is difficult to determine who paid 'what, when and for how much'. The amount a developing country has to pay for a drug can be a major determinant of morbidity. It is suggested however that in the future, drug transactions could be publically-listed for all interested parties to peruse (although this is very unlikely in the current capitalist climate worldwide), allowing for increased competition in the marketplace and fairer pricing across the board.

In the ideal world, any individual, at any given time, should have access to proper health care, as stated in numerous international declarations on human rights. This should be the determining principle when it comes to obtaining drugs, although the economic models generally do not allow for such a situation at present. The Kuwaiti Government should study and analyses the mentioned factors to achieve a suitable prices for both consumers and companies.

#### 5.1.2.4 The Quality Assurance (QA) Department

The Quality Assurance Department is part of the Drug and Food Control Administration, and belongs as part of the Drug Control Supervision. The links in

this way however do cause problems, because of conflict of interest and this is suggested to be a large issue. As a result it was proposed in the discussions with the staff (in informal visits to the Department during the PhD study), that the QA Department would be best located as an individual department because of the overlap which results from its duty to control, monitor and evaluate the other Supervisions and Departments. (KMOH, 2014 c)

The functions of this department are:

1. Working on insuring the quality, safety and efficacy of the drugs.
2. To ensure that the drugs/medicines entering the country are registered drugs and insure that there are not any recent adverse effects from them.
3. Controlling and Monitoring the registration and laboratories supervisions and working towards having in place an efficient Post Marketing Surveillance system.
4. Carrying out inspections and reporting on suspect counterfeiting drugs in Kuwait's marketplace.
5. Reviewing studies for the safety of food supplement products according to WHO conditions.
6. Ensuring that the working of the laboratories is under GLP conditions. (KMOH, 2014 c)

The issues found in this department are:

1. Lack in the number of health staff, for instance the number of working staff of the Quality

Assurance Department is only two pharmacists.

2. Shortage in the provision of training programs in quality assurance, management and safety

studies for the health professional staff.

3. The Department should be independent and divided from Quality Control Supervision.

4. The KMOH should be providing greater powers of authorization to the Department to insure there is enough control over the Quality Control and Laboratories. (The Quality Assurance was discussed in details in Chapter 6, page 255.)

5.1.2.5 Drug Release Office in Kuwait International Airport

This office is responsible for releasing all the imported drugs which arrived in Kuwait Airport. It releases products for both public and private sectors, but not for the products of the Central Medical Store because they have their own office in the airport. This office is responsible therefore for release for the shipments and parcels (KMOH, 2014 d).

The issues found in visiting this Department by the structured interview are:

1. There is not enough staff, as there is only: 1 pharmacist and 4 technicians working in the Department.
2. There is only one store and it is not large enough for all the storage requirements and the store is not under the GMP condition.
3. Insufficient facilities of IT connection between the Office and the Drug Control Administration.
4. They should have their individual department for personal parcels.

As a Summary to the information above; it can be suggested that by amending the problem issues in the system of the Drug and Food Control Administration it is likely it will result in an increase and improvements in the quality and efficiency of the work in this administration, and it will help to reduce the errors in the work. It is likely that the development of the Administration will accelerate once there a completion of work on the establishment of the NDP in the right way.

### 5.1.3 Drug Inspection Administration

As mentioned above the KMOH issued a Ministerial Decree No.166, for the establishment of the Drug Inspection Administration in 1985, to ensure enough control over the pharmaceutical sector (KMOH, 2011 f). The main function of this Administration is to inspect and monitor all the public and private health areas (pharmacies, drug stores, industries and drug companies) and other places where the medicines are traded with the population, to ensure that the medicines used are safe for human use and are registered under the full conditions of the KMOH rules.

The organization structure of a Drug Inspection Administration is divided into two Supervisors:

1. Inspection supervision.
2. The supervision of licensed materials, narcotics and psychotropic substances.

#### 5.1.3.1 Inspection supervision

Consists of four departments which include:

a). Department of Public Inspection:

whose duty is to supervise the inspection and observation all the pharmacies and medicines stores which are linked to the KMOH and the work of their regulatory staff, as well as having control of the annual inventory of drugs and ensuring the validity of the data and results.

Also it is their responsibility to inspect the public pharmacies in the public hospitals and wards, health clinics, the pharmacies of the Military Hospital, pharmacies of the Internal Forces Health Clinic, pharmacies for the elderly and disabled people which belong to the Ministry of Social Affairs and the pharmacy for diabetics in the Dasman Diabetic Institution.

The number of inspectors working in this Department are only 6 Pharmacists and they are responsible for inspecting 316 public pharmacies which are registered under the KMOH, also the medicines drug store of the CMS and in addition they have a large commitment to keeping the paper and office work under control, where electronic records are still not in place in this section of the KMOH. The average number of inspections which are required for each public pharmacy is 4-5 times yearly, which can be greater than this number where there are requirements for addition more inspection visits in cases where there are complaints from the consumers (KMOH, 2014 e).

b). Department of Private Inspection:

It is responsible for monitoring the private pharmacies to ensure that the drugs are registered and approved by the Kuwaiti Drug and Food Control Administration, this action has the effect of prevention of the spread of counterfeiting drugs to the population. It also can ensure that the pharmacies have a license and that their employees are registered with the MOH. They also ensure that the medicines are purchased under the ministerial pricing controls and the dispensed drugs are sold in relation to medical prescription. Also this Department is responsible for inspection of the local pharmaceutical industries and the private medical stores to ensure that they operate under Good Manufacturing Practice (GMP) and under the ministerial roles (KMOH, 2011 g) (MSC, 2011).

It is also the responsibility of this section to inspect all the private pharmacies in private hospitals, health clinics, drug companies, private drug warehouses and drug industries. The numbers of inspectors in this department are only 9 pharmacists, and there are 3 inspection teams working in the morning, afternoon and evening and their work includes: 450 pharmacies, 40 warehouses and 20 hospitals (KMOH, 2015 e).

Each team normally consists of 2-3 inspectors and the average number of inspections for each private pharmacy is 4-5 times yearly. In addition there can be more inspection visit for private pharmacies where there are complaints from the

consumers. For example the total number of all inspections for the private sector in 2013 was 2123 inspection visits, as detailed in the Table 5.1.

**Table 5.1 The total number of all inspection visits to the private pharmacies (and Public/Private stores in 2013 was 2123 as broken down below (KMOH, 2013 a).**

| Governorate | Capital Health Area | Hawalli Health Area | AL Ahmadi Health Area | AL Jahra Health Area | AL Farwaniya Health Area | Public/ Private Stores | Total |
|---|---|---|---|---|---|---|---|
| **Jan** | 27 | 76 | 26 | 15 | 57 | 10 | 209 |
| **Feb** | 16 | 36 | 42 | 15 | 10 | 8 | 127 |
| **March** | 28 | 59 | 41 | 16 | 52 | - | 196 |
| **April** | 24 | 93 | 43 | 37 | 40 | 20 | 244 |
| **May** | 30 | 70 | 26 | 21 | 40 | 13 | 197 |
| **June** | 20 | 56 | 34 | 23 | 26 | 22 | 181 |
| **July** | 15 | 67 | 26 | 9 | 37 | 12 | 166 |
| **Aug** | 13 | 38 | 16 | 5 | 24 | 12 | 108 |
| **Sep** | 17 | 68 | 34 | 29 | 48 | 3 | 199 |
| **Oct** | 23 | 61 | 28 | 9 | 33 | 12 | 166 |
| **Nov** | 17 | 50 | 28 | 14 | 34 | 7 | 150 |
| **Dec** | 13 | 74 | 38 | 13 | 35 | 7 | 180 |

These inspections should cover technical workings e.g. lighting, temperature and hygiene control. Also they check the Pharmacy License, the employment license, the storage conditions, prices of the purchased drugs and compare them with the prices on the MOH list. The inspectorate also examines medical preparations such as creams and drops which are prepared in the pharmacy. Overall they insure that all the purchased drugs are under the control and are registered with the MOH.

c). The Department of Herbal and Veterinary Inspection: is working to control, regulate and monitor all the herbal and veterinary products which are available in the private hospitals and the private veterinary clinics, to ensure that the herbal and veterinary drugs are under the regulation, qualifications of registration and requirements of KMOH and to adjust and confirm that the licenses are valid to practice the Profession of Pharmacy in the areas of veterinary medicine.

This Department is relatively new and was established in 2005, and the work effectively started in 2011, the number of Pharmacist health professionals is 4. (KMOH, 2011 h) (MSc, 2011)

d). Department of Statistics follows up and filing. (KMOH, 2011 l)

5.1.3.2 The supervision of licensed materials, narcotics and psychotropic substances

This Section is answerable for regulation, follow up and monitoring for illegal and unregistered dispensing of narcotics and psychotropic drugs in the private sector.

This supervision consists of two departments:

1. The licensing department of materials and products of psychotropic substances.

2. The Licensing Department of Narcotics Substances and Preparations. (KMOH, 2011 i)

This administration was visited during the PhD study and structured discussions (interviews) were carried out with the Pharmacist staff (Further details of these discussions and number of staff involved can be found in chapter 4); and it was found that there were a number of issues in the working system, these included:

1. There is a lack of an electronic system in the Drug Inspection Administration, where there is a limited link between this Administration and the Drug and Food Control Administration. Because of this a large number correspondences had to be carried out by manual means which is very time consuming, to establish new registered drugs and to update the existing data.
2. The lack of a full internal IT system (e.g. laptop or simply i-pads) for easy communication within the administration which can extend the time taken to carry out an inspection, because of the lack of all the required information during an inspection.
3. Insufficient number of inspectors and staff, there are only 25 inspectors in total in the Administrations and they are responsible to inspect and carry out checks on the controls for all the public and private pharmacies. These inspectors also carry out a large number of inspections for each pharmacy or related unit each year, which is higher generally than in other countries.
4. It was also mentioned that the inspectors did not generally have access to training and update training programs for the staff. This is especially true for access to GMP assessment courses.

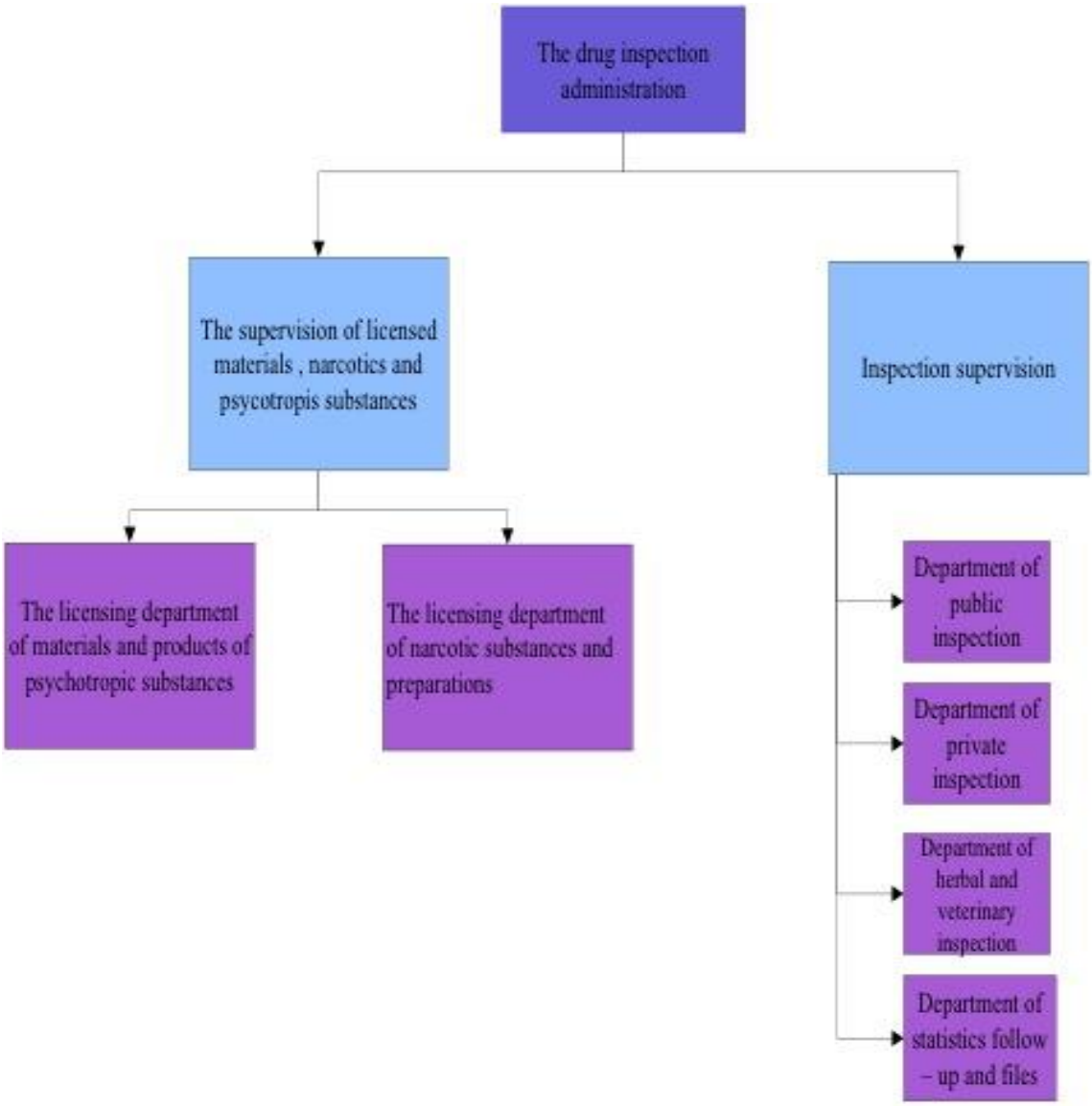


**Figure 5.5 Organization structure of Drug Inspection Administration (KMOH, 2011 i) (MSC, 2011).**

5.1.4 The Central Medical Stores Administration

The Central Medical Stores Administration (CMS) was established in 1985, according to the Ministerial Decree .166, and it was regulated in 2005, according to the Ministerial Decree 287.

This Administration specialized in the regulation of tasks relating to the Affairs of Medicines, Medical Consumables and Laboratory Materials, and work related to

the distribution of these products to all public hospitals, health clinics and health centers in the State of Kuwait (KMOH, 2013 m).

The duties and functions of this Administration are to:

1. Ensure the access needs of the State are provided for through medicines requirements and by implementing programs that ensure supply in accord with the drug policy.

2. Apply the KMOH plans for provision of medicines and that sufficient are in storage to deal with the needs of the population at any one time and to ensure the availability of the medicines at all the times.

3. Implementation of Drug Procurement and Purchasing Policies in order to ensure the availability and affordability of a range of several kinds of medicines to treat conditions.

4. Ensuring an adequate supply of essential medicines, especially for possible emergency cases and to have in place strategies which can deal with any shortage of drugs.

5. The provision of suitable storage areas, which operate under the documented storage polices, standards and conditions to ensure the safety of stored drugs and to implement, control and monitor these stores.

6. Limitation the annual needs of the Ministry to the medicines, medical supplies and laboratory supplies.

7. Preparing the required and necessary annual budget to meet the health needs of the population within Kuwait and exercising control over the overall medicines expenditure within the financial restrictions of the KMOH and for the medical and pharmaceutical products, materials and equipment.

8. Preparing Procurement tenders for medicines, medical supplies and laboratory material and concluding medical contracts in accordance with the Kuwaiti rules and regulations.

9. Preparing the suitable programs for purchasing, storage and distribution of the medicines, medical supplies and lab materials.

10. Preparing a special record of accepted supplies companies and local agents for the approved multinational and international drug companies.

11. Working with the application instructions of the Ministry of Finance on the contract for the supply of medical materials, which is divided into:

a). Buying directly (Requirement), if the price is below 15000 USD.

b). Buying indirectly (Contracts), if the price is more than 15000 USD.

12. To prepare inventory assets of drugs, medical supplies and laboratory materials in all the public hospitals and clinics, which is normally carried out without prior notice, at least once a year through the inventory drugs committees.

13. Supervision of suppliers records and collection of all required data about the medicines and companies, which is then categorized to include observations of any future savings and for the updating of archive data.

14. Reviewing and following-up the provision of the special drug orders and noting of unavailable medical supplies in the State of Kuwait.

15. Preparing the documents associated with the donation of drugs and medical supplies to support stricken states, based on the recommendations of the Kuwait Cabinet. (KMOH, 2013 b)

According to the Ministerial Decree No. 287 of 2005 which examined the reorganization of the CMS, the administration should be based upon five supervisions (KMOH, 2014 f), which includes:

1. The Drug Supervision.

2. The Medical Supplies Supervision.

3. The Laboratory Supplies Supervision.

4. The Store Supervision.

5. The Finance Supervision.

5.1.4.1 The Drug Supervision

The mission of this supervision is to provide the medicines for all public hospitals and public health clinics, and to ensure the validation of the drugs before receipt, storage and distribution (KMOH, 2011 i ) (MSc, 2011).

The Drug Supervision is further divided into five departments:

1. Injection Department.

2. Drug Department.

3. Medical and Pharmaceutical preparations Department.

4. Kidney and Vaccine Department.

5. Narcotics Department.

The Departments of this supervision have specialized knowledge in:

a) Provision in the needs of the hospitals and health centers for specific drugs which ensure the continuous regularity of availability, by following-up of dispensing rates and drug validity.

b) Requesting prices and offers from pharmaceutical manufacturing companies or from local agencies.

c) Following-up storage and supply of medicines according to the approved systems.

d) Preparation of annual requirements related to the medicines needs of the KMOH.

e) Follow-up drug inventory rates. (KMOH, 2014 g)

5.1.4.2 The Medical Supplies Supervision

This supervision is concerned with ensuring the provision of consumables and medical devices, such as ligament surgery, rubber products, sutures, x-ray films, materials for sterilization, syringes and intravenous needles and other consumables (KMOH, 2011 j) (MSc, 2011).

The Medical Supplies Supervision is divided into three departments:

1. Medical Disposal Department.

2. Ligament Surgery Department.

3. Dentist Products Department.

The Departments of this supervision are specialized in:

a) Ensuring the required specifications are addressed for medical consumers, ligament surgical, dental materials and medical supplies.

b) That the needs of the hospitals and health centers are provided for in terms of the medical consumers and to ensure that there is a continuous regularity of availability, with follow-up dispensing rates and drug validity.

c) Preparation of annual drugs requirements in line with the needs of the KMOH. (KMOH, 2014 m)

5.1.4.3 The Laboratory Supplies Supervision

Has a remit to provide the laboratory products as required by the public hospitals and health clinics (KMOH, 2014 h).

The Laboratory Supplies Supervision is divided into two departments:

1. Laboratory Disposal Department.

2. The Solutions and Laboratory Materials Department.

5.1.4.4 The Store Supervision

This supervision regulates all the received, stored and distributed products (KMOH, 2013 b).

The Store Supervision is divided into three departments, as:

1. Receiving Department.

2. Storage and Distribution Department.

3. Follow-Up Contracts Department.

The departments of this supervision are specialized in:

a) Supervising the work of the receipt, storage and distribution of all the lists of materials.

b) Verifying the integrity of the examination procedures of the imported materials and compliance with specifications and technical conditions in the contracts.

c) Verification of the safety of stored materials by appropriate conditions.

d) Participation in the work of the inventory in the CMS. (KMOH, 2013 b)

5.1.4.5 The Finance Supervision

Its divide into four departments:

1. Accounting and Auditing Department.

2. The Budget Department.

3. Contracts and Purchase Order Department.

4. Tenders Department. (KMOH, 2011 k)

The Departments of this supervision are specialized in:

a) Preparation of the draft budget for the administration jointly with concerned authorities, and sending it to the competent authorities and following-up of the implementation of the budget.

b) Ensuring the application of laws, regulations and the financial system.

c) Implementation of purchase orders and contracts concluded between the CMS and suppliers.

d) Preparation periodic reports on the annual requirements of the materials and labor to be provided.

e) Preparation of final and periodic statement accounts and processing of different management activities. (KMOH, 2014 i)

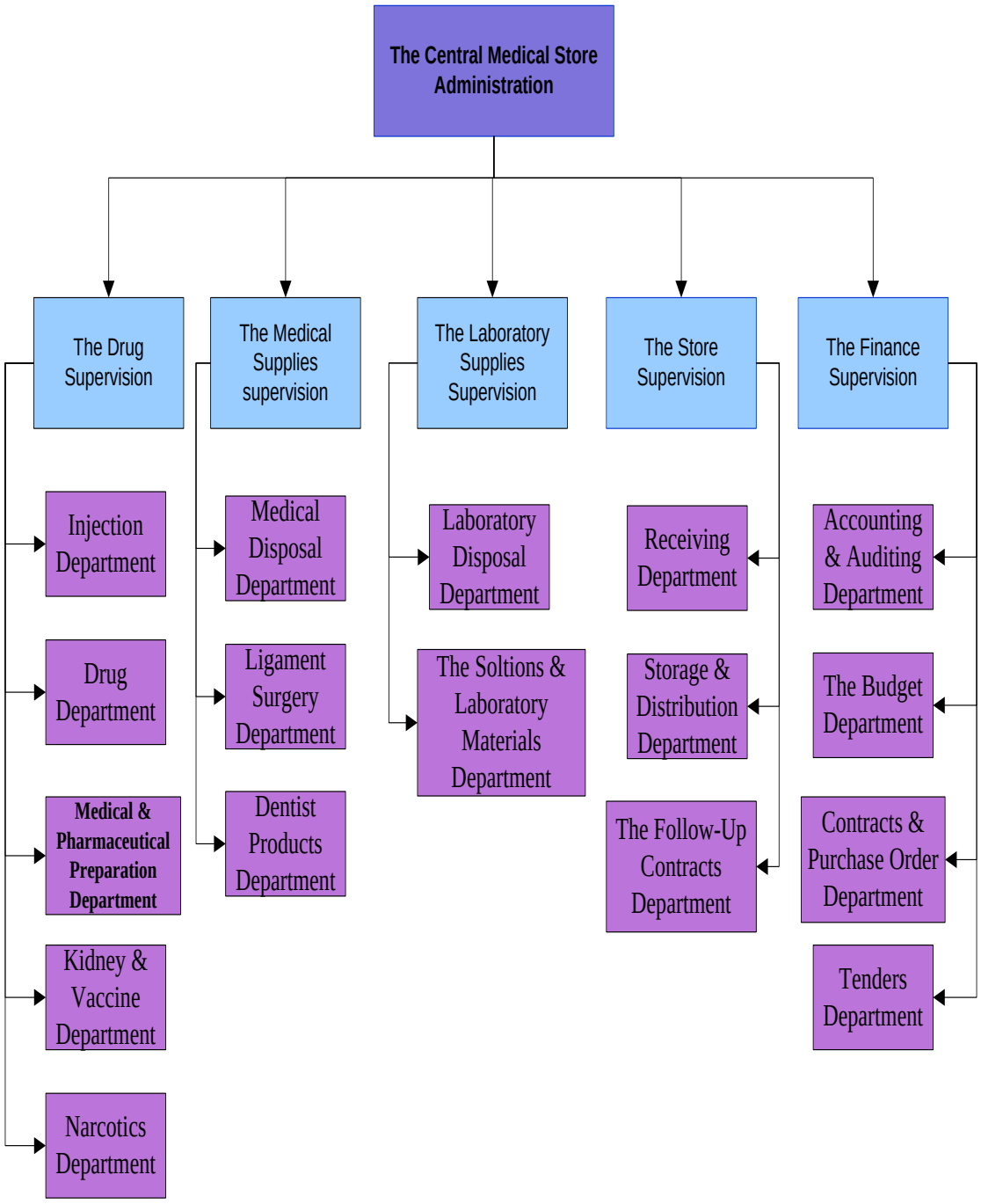


**Figure 5.6 Organization Structure of Central Medical Stores (KMOH, 2011) (MSc, 2011 l)**

- The main functions of the CMS are:

1. Purchasing the drugs.
2. Storage the drugs.
3. Distribution the drugs.

1. The purchasing of the drugs: is the activity which provides the needs of the drugs, medical supplies and lab materials for the MOH at the best quality and price.

The purchased products were divided into two parts:

a) The Regular Materials, where the stock is normally more than 8 months and must be available on a permanent basis, in the appropriate amount and exist in the items catalogue. It also includes all current deemed drugs as the essential medicines.
b) The Irregular Materials, which should be available every year according to the requirement of the Medical Boards. It had private specifications such as: shelf life, quantity of the materials, usage and re-request. (KMOH, 2015 f)

The purchasing of irregular materials can be done through:

1. Special orders, through the Special Order Department in CMS. The function of the Department is to order and purchase medicines for patients if the medicines are not available in both public sector and private sector in State of Kuwait (This however can be a very expensive method of obtaining medicines which are often purchased for a small number of patients e.g. for some cancer diseases and when the drugs are not registered in any local companies in Kuwait). There are two offices for the special orders one in London and one in Washington.

2. New item orders.

The purchasing cycle for the regular materials should be based on: (1) The integrated database and (2) study the optimal use of resources (KMOH, 2015 f).

The integrated database includes:

- Statistical material.
- Current inventory.
- Existing orders.
- Demands rate.
- Usage rate.
- Cost prior.
- Suppliers who are available.
- Shelf life of the material.
- Fluctuations in the pattern of consumption. There is no justification?

In the system of the purchasing cycle for the irregular materials, there is no prior integrated database but it is started as an integrated database after the first purchase order.


**Figure 5.7 The Purchasing Drug Cycle in the CMS (KMOH, 2015 f).**

2. The storage cycle of the drugs: there is only one store in the CMS for the storage of the drugs and it is under the GMP conditions.

In Kuwait Airport there is a Drug Release Office which belongs to the CMS, and is responsible for release of all the drug shipments from Airport Customs Department and which then transfers the medical materials to the CMS (KMOH, 2015 g).

There is tender storage every 3 years in the CMS where specialized storage companies, compete with each other to provide the best offer for the CMS, and the company which acquired storage tender will be responsible for arranging the drugs storage in the warehouse of the CMS, and its functions supervising of the:

1. Arranging the drugs storage in the CMS.
2. Providing the necessary employments and IT electronic system only for the work of storage drugs/medicines, medical consumables and laboratory materials in the warehouse of the CMS (without any electronic link system with other internal or external health areas).
3. Classifying the storage drugs according to their usage, efficacy and type.
4. All the drugs should be stored under the GMP conditions.
5. Preparing the orders for the distribution. (KMOH, 2015 g)

The temperatures in the storage areas are set up so that drugs can be stored at their optimum temperatures and the temperature variation are in 5 forms.

1. – 15 c.
2. 2-8 c.
3. 14 c.
4. 18 c.
5. 21 c.

The types of storage are:

a) Steel Pallet for storage the bulk items.
b) Containers for medium bulk items and volume items, because of their size can be move on the basis of bulk picking which can allow relatively easy transfer of materials to outside the store. It can be:

- Gliding Containers (CG): used to storage the bulk items and can contain up to 7 containers with same shelf life and barcode for the same material.
- Container Rack (CR): used to storage the bulk items and it contain only one container.

c) Gliding Boxes can contain 10 boxes in each area and it has the same shelf life and barcode for the same material. It is used for transferring bulk loads.
d) Small multiple shelves are also used for storage the small materials.
e) Drawer Cabinet (Modular Steel Cabinet) used to store the micro materials and small sized (KMOH, 2015 h). This information suggests that a full range of storage facilities is available in CMS.

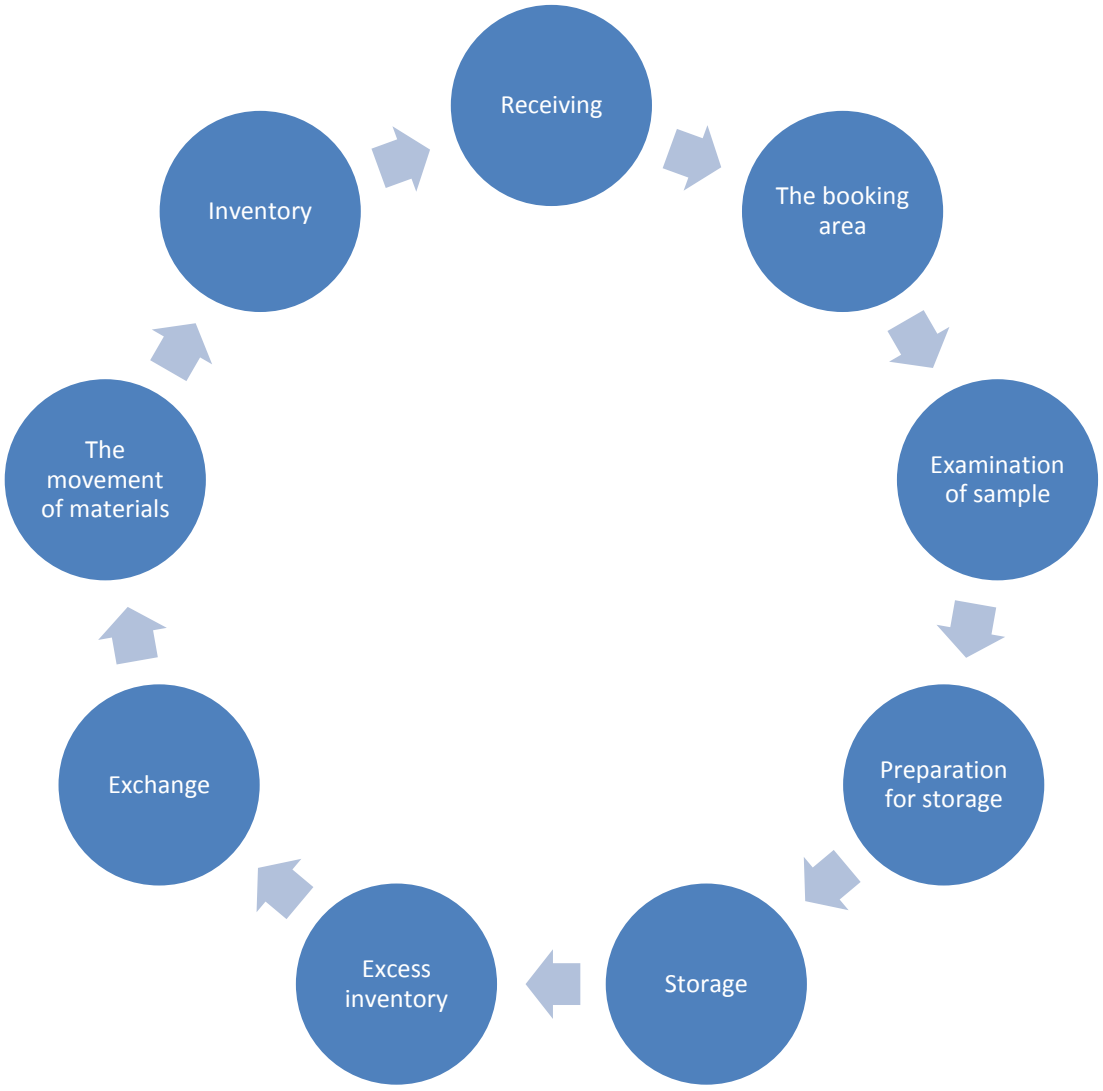


**Figure 5.8 The Storage Drug Cycle in the CMS (KMOH, 2015 g).**

3. The Distribution of Drugs:

The CMS administration is responsible for distributing of medicines to the public general hospitals and clinics:

1. Six General Hospitals.
2. Nine Specialized Hospitals.
3. Thirteen Specialized Clinics.
4. Ninety three General Medical Clinics (Additional information in chapter 4, page 12-14) (KMOH, 2015 i).

There are 2 types of Drug Distribution:

1. Normal distribution, where the drugs are distributing every 2 weeks to the public pharmacies in hospitals and clinics.
2. Urgent distribution, which is for urgent orders and can be used every day for only for 3 items or less.

There are also other distribution procedures for:

1. Medical gases and they are transported every week.
2. Narcotic drugs and psychotropic substances are distributed according to need.

All the medicines are distributed by the refrigerated trucks which belong to the CMS (KMOH, 2015 i).

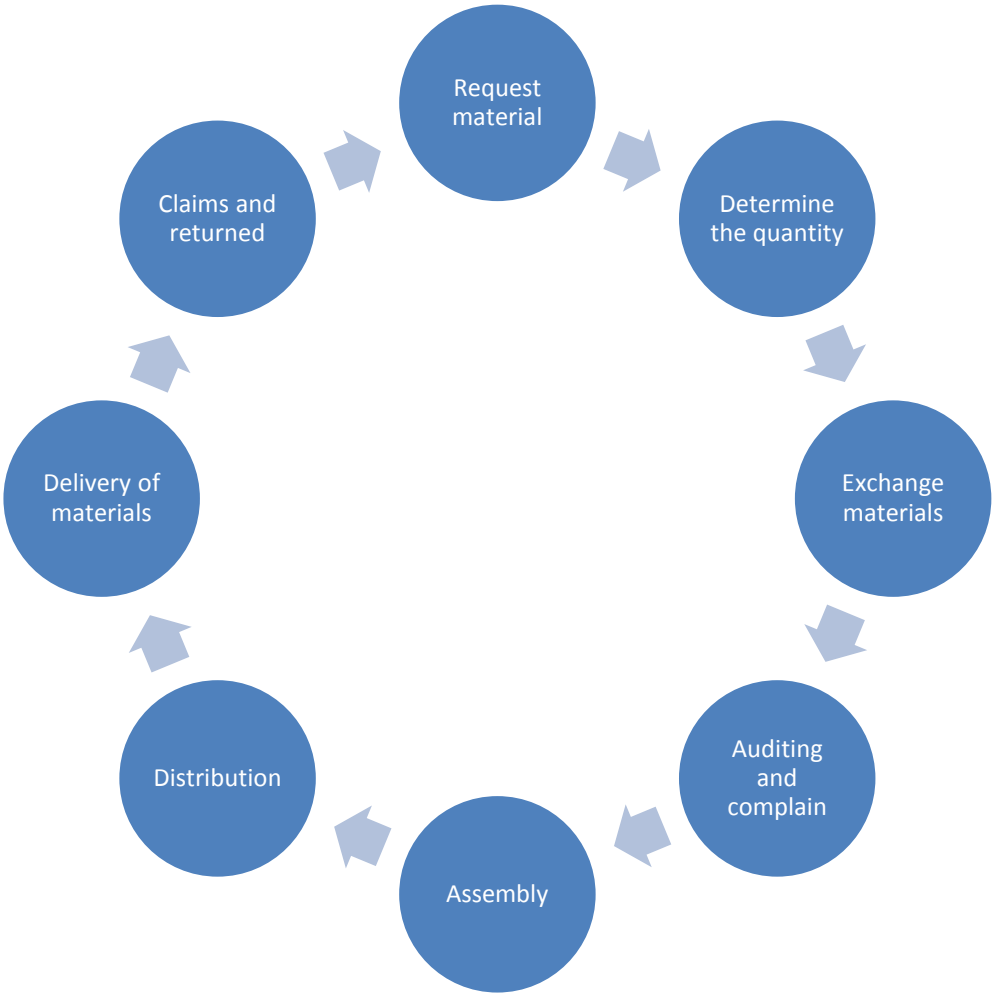


**Figure 5.9 The Distribution Drug Cycle in the CMS (KMOH, 2015 i).**

The general budget for the CMS from 1/4/2013 to 31/3/2014 was 903 million US dollars, and the allocated budget for the purchased of drugs (which includes: Injections, oncology medications, specialties products, nutrition products, vaccines, tablets, diabetic drugs, respiratory drugs, neurology drugs, chemicals products, psychiatric drugs and kidney department products), was 644 million US dollars. This expenditure is very large when compared with countries of equivalent size to population in Kuwait (for example, Bahrain and Qatar) and its indicated that the KMOH spent high amounts of money. One major way to save on the State budget would be to introduce an Essential Drug List (for more details see Chapter 6).

In addition it was found that there was a large wastage of medicines and it was found that the total amount of the expired drugs in the CMS from 01/01/2013 to 31/12/2013 was estimated to have reached 5,75 million $ (See Table 5.2), and this is a great amount of loss on the State budget, which could otherwise be used in other health projects and the MOH can take benefit from it (KMOH, 2013 c)

The main reasons for the occurrence of expired drugs in the CMS were:

- Lack of Essential Drug List in the CMS.

- The short shelf life of the most ordered tenders.

- The physicians and consultants in the public hospitals ordered products and after short time they changed their order and asking for different drugs. (KMOH, 2013 c)

According to the collected data, informal visits and discussions (structured interviews) with the health professional staff of the CMS administration during the PhD course (Further details of these visits, discussions and number of staff involved can be found in Chapter 4, page), the researcher was alerted to the existence of some problems, needs and requirements (see below) that don't help in the work in the Administration and could cause hindrance for the implementation of a NDP. The problems found and needs in the CMS included:

1. The policy of the government puts pressure on the CMS to purchase generic drugs from non-qualified manufacturers especially from GCC countries.
2. All the items were stored in one store, since 1982 the CMS didn't increase the number of stores.
3. The need for more staff especially pharmacists.
4. The need of more training programs for the staff.
5. Establishing Essential Drug List to better use the budget and determine appropriate needs of medicines.
6. Need for an IT electronic link between the CMS and Drug Control Administration and the pharmacies in public hospitals and clinics.

7. To have more centralization in the work.
8. To establish a Cost Effectiveness Department.
9. To have an official electronic information web page.

In order for to solve these issues, meet all the necessary requirements and give support to improve the efficiency of the work it is proposed that the KMOH should develop the administration system, because it could reflect positively in the establishment of a NDP and the development of the Health Care System.

**Table 5.2 The cost of expired drugs in CMS from 01/01/2013 to 31/12/2013 (KMOH, 2013 c).**

| Expired Product | Cost in US Dollars | Expired Product | Cost in US Dollars |
|---|---|---|---|
| 1. Injections | 537 thousand $ | 7. Diabetic Drugs | 2,744 $ |
| 2. Oncology medications | 303,5 thousand $ | 8. Respiratory Drugs | 293,6 thousand $ |
| 3. specialties Products | 3 million $ | 9. Neurology Drugs | 89 thousand $ |
| 4. Nutrition products | 111 thousand $ | 10. Chemical Products | 2,135 $ |
| 5. Vaccines | 2,600 $ | 11. Psychiatric Drugs | 232,8 thousand $ |
| 6. Tablet | 963 thousand $ | 12. Kidney Department Products | 139,6 thousand $ |

## 5.2 The Private Sector

As mentioned in the previous chapter (Chapter 3), the private sector is very important part of the health services in Kuwait and it's complementary to the mission of the public sector. To get high standard level of a NDP in the future and to ensure success of the establishment of this organization in Kuwait, the KMOH should give attention to the private sector and involved it in the work of

implementation a NDP to take benefits and advantages of their experiences, suggestions, advice and views of health professionals in this sector. Also the KMOH should listen to their needs, concerns and requirements which are often related to the regulations and legislations set out by the KMOH, and to developed and improved the health services in both public and private sectors. This section will explain the private sector in Kuwait and focus on the most important weakness points to help support, understand and find solutions for the issues of this sector in the future.

In 2015 the number of the private pharmacies in Kuwait was 450 (KMOH, 2015 h), where they were distributed around all the governorates of the country (See Table 5.3) and divided into 3 groups, includes;

1. Private pharmacy belongs to the individual persons or private companies, and it was reached to 365 pharmacies.
2. Private pharmacy belongs to cooperatives societies, where it's up to 66 pharmacies.
3. Private pharmacy belongs to the private hospitals, where it was reached to 19 pharmacies.

The growth of the population, the needs of medicines and increasing use of patients of treatment in the private hospitals and clinics is likely to lead to an increase the number of the private pharmacies in Kuwait, to meet the needs of consumers and follow the development of the health investment of this sector.

According to a study which projected the future by the KMOH it is likely that there will be an increase of the number of private pharmacies every year, for the next five years (KMOH, 2015 i). Table 5.4 shows the expected number of the private pharmacies in Kuwait.

**Table 5.3.The number of private pharmacies in State of Kuwait to 2015 (KMOH, 2015 i)**

| Governorate | No of Private Pharmacies | NO of Private Pharmacies Belong to Cooperative Societies | No of Private Pharmacies Belong to Private Hospitals | Totally |
|---|---|---|---|---|
| **Capital** | 28 | 18 | 2 | 48 |
| **Hawalli** | 147 | 13 | 6 | 156 |
| **AL Farwaniya** | 84 | 11 | 1 | 86 |
| **AL Jahra** | 37 | 10 | 1 | 42 |
| **AL Ahmadi** | 69 | 14 | 9 | 82 |
| **Totally** | 365 | 66 | 19 | 450 |

**Table 5.4 The expected number of the private pharmacies in Kuwait (KMOH, 2015)**

| Year | Expected NO. Of Pharmacy |
|---|---|
| Year 2016 | 465 |
| Year 2017 | 480 |
| Year 2018 | 495 |
| Year 2019 | 510 |
| Year 2020 | 525 |

5.2.1 Registration and licensing of the private drug companies in State of Kuwait

Before the private pharmaceutical companies and agents start working in the private market and dealing with drug trade in Kuwait, they should apply for a license from the KMOH. The Drug and Food Control Administration is responsible to give registration and licensing for the private drug companies in State of Kuwait. The objectives of this aspect are to regulate the private sector, ensure that the drug distributors are under the conditions of KMOH, and ensure that all the drugs in the private market are quality and safe for the users and its support to be the private sector under control and monitor of the KMOH.

The Registration Requirements for the licensing of the private pharmaceutical companies in State of Kuwait includes:

1. Company name and country of origin.

2. Letter of appointment, it should be original and legalized from Kuwait Embassy in the country of origin.
3. Pharmaceutical Manufacturing License, it should be original and legalized from Kuwait Embassy in the country of origin.
4. GMP certificate, it should be original and legalized from Kuwait Embassy in the country of origin.
5. Date of establishment, registered capital and company turnover for the last 3 years.
6. Number of manufacturing sites owned by the company (Name and address of manufacturing sites to be registered).
7. Number of employees and their qualification.
8. Site Master File.
9. Type of activities (Researcher, Developing, Manufacturing and packaging).
10. Manufacturing lines to be registered (solid dosage forms, semisolid dosage form, ophthalmic/nasal products, biotech products, liquid dosage form, parental, aerosol dosage form or other).
11. List of product marketed.
12. List of countries where its products are marketed.
13. Layout and flow diagrams of manufacturing lines.
14. If the company is centrally registered in GCC (Required GCC Central Registration Certificate).
15. The company is FDA approved (Required Evidence of FDA approval).
16. The company is EMEA approved (Required Evidence of EMEA approval).
17. The company is MHRA approved (Required Evidence of MHRA approval).
18. Any inspection visit reports.

- The conditions for the pharmacy license in the State of Kuwait:

1. The owner of the pharmacy should be a Kuwaiti pharmacist.
2. The pharmacist should be registered in the Kuwaiti Drug Association.
3. The pharmacist should have at least 5 years experience. (This was changed in the last 3 years as it was 2years before this time).

4. The pharmacist should pass a license exam from The MOH to get a private pharmacists license.

5.2.2 The Property Rights for the private pharmaceutical companies in State of Kuwait

In 1994, at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) the Trade – Related Intellectual Property Rights (TRIPS) agreement was established. The TRIPS agreement is an integral part of the World Trade Organization (WTO) Agreements and became the most comprehensive international Instrument on International Property Rights (IPRS).

The TRIPS agreement includes:

- Geographical indications.
- Copyrights and related rights.
- Trade marks.
- Patents.
- Industrial Designs.
- Layout designs of integrated circuits. ( William, 2001 )

These regulations have been issued to regulate and organize the drug market and to protect the property rights of the pharmaceutical companies and industries.

According to the Ministerial Degree No.675, for Year 1998, which is based on the agreements of the State of Kuwait with GATT, WTO and TRIPS, and also based on the development of adequate standards and principles to protect the Property Rights of the pharmaceutical products, companies and local agents, the KMOH decided to:

1. Prevent any drug registration if it contains the same chemical composition and therapeutic effects with another drug, still under the period of Property Rights.

2. If the local agents want to register any pharmaceutical product under the Property Rights, they should submit a:
    - CPP Certificate which shows the registration date, the scientific name and trade name of the pharmaceutical product, and needs to mention the remaining period of product Property Rights in the country of origin. (This should be the original document and should be legalized from the Kuwait Embassy in the country of origin).
3. The KMOH have the right to except the registration of some products under the Property Rights and import the product in special cases such as:

A. If the KMOH can prove the exploitation of some pharmaceutical companies of the product Property Rights to increase the product price in Kuwait when compared with the prices in other countries, especially in GCC countries.
B. If the KMOH can prove that the product under the Property Rights is not in conformity with the international standards and non-suitability for use.
C. If the KMOH can prove that the pharmaceutical company that owns the Property Rights of the drug is not committed to supply contracts for both public sector and private sector, or not committed to the required conditions of the MOH contracts.
D. If the pharmaceutical product under property rights is needed for the country in emergency cases, wars and in accordance with the public requirements.

The KMOH property rights regulations have emerged from the recent TRIPS agreement, which were issued to assist the developing countries, for example:

- On November 2001 during the WTOs Fourth Ministerial Meeting at the Doha declaration, TRIPS Agreement it was approved to have safeguards which can protect developing countries, such as:

- Compulsory licensing which allows the production and sale of generic drugs before expiry of the patent, in emergencies.

- Polar provision which allows testing and regulatory approvals of generic drugs before the patent expires so that the drug is ready for production and sale.
- Parallel importation allows a country/pharmacy unit to shop around for a good price to increase competition.

- On August 2003, The TRIPS meeting in Thailand agreed to give permission to Brazil, Thailand and South Africa to have a full authorize of providing HIV patented drug by their own companies. This is to get the medication to the largest number of people at the earliest time (Subramanian, 2004).

- On 6 April 2004- The Global Fund, The World Bank, UNICEF and Clinton foundation meeting announced that the developing countries will have guarantees of payment to support purchasing HIV medicines at lowest prices at more than 50% less than its available price and to ensure the security of drug distribution (UNICEF, 2004).

- On 2002 The Trade Promotion Authority (TPA) recommended that new trade agreements negotiated by the USA shall respect the Doha declaration on TRIPS and Public Health (WHO, 2004).

### 5.2.3 The trade penalties for the private sector

The KMOH has issued a number of trade penalties in order to prevent or reduce the excesses and misuse of the systems in the private sector, also to protect the consumers from greed of some companies and to ensure control over the private drug market and private sector in the country (KMOH, 2012 a).

The trade penalties for the private sector in Kuwait, includes that there shall be punishment:

1. By imprisonment for a period not exceeding two years or fine not exceeding three thousands KD (10,600 USD) or by both of them if:

- A practicing profession pharmacy operates without a license from MOH or obtains a license through an incorrect way.

- Establishment of private pharmacy, warehouse, pharmaceutical industry or research centre without a license from MOH or obtained through an incorrect way.

2. There shall be punished by imprisonment for a period not exceeding two years or a fine not exceeding two thousands KD (7000 USD) or by both of them if:

- There is a violation of drug pricing decisions.

- The licensed premises are used for other purposes.

3. Shall be punished by fine not exceeding two thousands KD (7000 USD) if:

- There is violation of advertising and promotion decisions of the pharmaceutical products.

4. Shall be punished by giving a warning, suspension from work for a period not to exceed one year, cancellation of the license to practice the profession, closure of the premises not exceeding six months if:

- There is violation of the rules regulating the registration process of the pharmaceutical products and the medical devices.

- The pharmacy sale of any pharmaceutical product is not from a source which is a registered local agency in Kuwait.

- Sale of any pharmaceutical product which is not-registered in a Kuwaiti Drug Control Administration for the private market.

5. Shall be punished by imprisonment for a period not exceeding 15 years or fine not exceeding 15 thousand KD (55,000 thousand USD) or by both of them if:

- Private pharmacy, company or store, sells non-registered narcotics and psychotropic substances.

- Private pharmacy, company or store dispenses non-prescribed narcotics and psychotropic substances.

-There is manufacturing or import non-registered narcotics and psychotropic substances.

5.2.4 The issues, problems and needs of the Private Sector in Kuwait

There have been frequent visits (during structured interviews) to the private pharmacies and pharmaceutical companies during the PhD study from 2012 to 2014, and during the discussion with the senior and junior staff who were working in this sector. During these visits it was found that the private sector needs to investigate many updating requirements and suffers from number of issues, such as:

1. Lack of pharmaceutical industries in Kuwait, and there should be talks to allow the international pharmaceutical industries to have licenses in Kuwait and also give them the opportunity to develop all the facilities to allow them to work and produce medicines in Kuwait.
2. There is a major need to establish a Kuwait Essential Drug List which helps the Local Medicine Companies to determine their purchases and to have a clear vision about choosing the appropriate medicines needs for the country.
3. Reduce the numbers of routine operations in the KMOH Administrations especially in: Drug Control, Drug Inspection and Central Medical Store, to speed up the work and give them more time to carry out additional work with more authority
4. To establish clear guidelines for the private sector work especially for drug registration, licensing and pharmacy and store conditions.
5. The delay in registration of new drug, where it takes 3 months or longer.
6. Delay in the decision making process from Regulators.
7. The need to deal with the Drug Counterfeiting problems and the need to strengthen the penalties.

8. Lack of economical knowledge from regulators on the industry and marketing.
9. The non-availability of a pharmacovigilance center in Kuwait.
10. Lack of a NDP in Kuwait.
11. There is shortage of a Drug Information Center and lack of national program for the increasing of people awareness
12. There is no strong control over the unlicensed drug advertising and fake drug companies.
13. The need for greater support for health investment in the State of Kuwait by

    providing information on official legislation, regulations and data concerning the health services

14. A proposal to link a system between all the administrative sections of the

    Ministry of Health which can lead to improved and increased collaboration within the health framework.

15. Also to establish an official electronic access site for the pharmaceutical administration to reduce the number of visits to these areas and to speed up the work by completing the required work electronically.

It is proposed that the work on providing requirements and solving issues related to the private sector will be a key supporter and will help the KMOH in implementing a NDP in Kuwait.

## Chapter 6.0: Discussion of the study results from the interviews and the visits to the facilities

From the research carried out there is effectively three main parts to the research study:-

● The examination of current operation of pharmaceutical supply and services, rules and regulations in Kuwait;

● A large number of interviews were carried with a wide range of health professionals in Kuwait to assess their views on the structure and delivery of pharmaceutical services.

● Visits to the main operational 'hubs' related to pharmaceutical delivery in Kuwait

The major outcome of the interviews (presented in Chapter 4) was the 100 percent response in favour of Kuwait developing and implementing a NDP. This result is a very important step for Kuwait and gives a lead for the MOH in convincing the government and with agreement for the country to start the continuous development of the Health Care System through the NDP, which should include both the public and private sectors. The responses provided in the study indicated, the NDP would strengthen, improve and encourage the health legislations and regulations to be more effective. They also clearly believed that a NDP can be act as a guideline for health professionals, which could facilitate better work practices.

The analysis of the interview results, suggested that there are a number of areas where there are concerns. One of main issues, which are discussed in greater detail in this Chapter, was the need for legislations and regulations changes and some of these are indicated below;

1. Weakness of some legislation and regulations in the Health Care System, in particular:

a) Drug registration in the Drug and Food Control Administration.
b) Weakness in control over the pharmaceuticals process (drug selections, drug cost effectiveness and high prices of drugs in the market) in both public and private sectors.
c) Issue with access to quality, safe and efficacious medicines in the State of Kuwait.
d) That the penalties for not adhering to the regulations and rules are weak in some areas and there is a need to strengthen penalties, in order to restrain the spread of rule breaking, such as the increasing numbers of counterfeit and unregistered drugs in the market.
e) That although Drug Procurement does follow a yearly cycle for many drugs, the open legislation on ordering of medicines by senior medical professionals does lead to budget imbalances and reductions in the overall drug cost/budget effectiveness.
f) The high price range and cost variability of medications in the private sector in the State of Kuwait.

2. The limited control in the selection of drugs and particularly the lack of an Essential Drug List.

3. The limited use of clinical guidelines in the choice of medicines supplied to patient and the increase in irrational prescribing and use of drugs in the State of Kuwait.

4. Insufficient training programmes and update sessions for health professionals.

5. Limited checking of Quality Assurance in the Drug and Food Control Administration.

6. Lack of a Pharmacovigilance Centre to gather world-wide data and reporting of problems/ patient response to medicines.

7. Major communication problems across the Pharmaceutical services resulting from a lack of IT/electronic systems linking the health areas of the KMOH.

8. Lack of a pharmaceutical industry in the State of Kuwait, which in its most basic form could produce Generic/ Natural Product Medicines to supplement those obtained from outside the country.

## 6.1 Improvement Legislation and Regulations of Health Care System in Kuwait

The Legislations and Regulations is the first step to establish a NDP in State of Kuwait, and it is necessary to developing, improving and strengthen the Legislation and Regulations of the Health Care System and the Pharmaceutical sector to ensure the primary ground for the NDP in the State, in addition to make it appropriate for future strategies plans.

In this section was discussed the following areas, includes:

1. Importance of Drug Legislation and Regulations.

2. Aim and main objectives of Drug Legislation and Regulations.

3. Drug Legislations and Regulations in State of Kuwait

### 6.1.1 Importance of Drug Legislation and Regulations

A NDP involves the control, coordination and procurement of pharmaceutical products, and as such there are area within which there is a potential for abuse and wrong use. Furthermore, a NDP provide a framework which can be used to allow the control of aspects such as import and export of pharmaceutical products,

their manufacture, marketing, prescribing and dispensing practices, distribution, and an overall enforcement of such laws and regulations (WHO, 2001).

For this reason, there is a need for development, improvement and updating the Drug Legislations and Regulations in Kuwait to support and control implementation of a NDP, where it is needed to implement and enforce the components of the NDP, where discussed in Chapter 1 and Chapter 6.

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In addition, Legislation and Regulations regarding drugs provides absolute recognition of the objectives and values of the drug policy and guarantees full support against activities carried out by individuals and organisations from the public or private sectors aiming to act outside of the stated policy framework. In these cases the DRAs are able to impose legal sanctions as a penalty for activities of this kind. Specific Legislation and Regulations should be passed aiming to define legal rights and responsibilities of the parties involved (health professionals, public health areas and private sector) and establish legal-binding standards for the control of health services activities (WHO, 2001).

Once defined the set of Legislation and Regulations should provide the regulatory authorities with control over premises, persons and practices involved in all aspects of research (clinical trials), manufacture, importation, licensing (patents), distribution, procurement, supply, marketing (promotion, advertising) and sale of drugs. Also it should be considered that a law is generally passed by a legislation body of a government, and are made as to meet the current and future needs that the country may have. Regulations on the other hand allow the authorities of the government to identify and define how the laws are implemented and enforced in terms of their interpretation (WHO, 2003).

### 6.1.2 Aim and main objectives of Drug Legislation and Regulations

- The aim of Drug Legislation and Regulations is to ensure that all the medicines reaching patients are quality, safety and efficacious (WHO, 2001).

- The main objectives are to ensure that all drug legislations and related regulations are up-to-date and meet the approved standards by:

1. Strengthen the medicines control.
2. Developing Drug Registration System.
3. Promoting the QA (Quality Assurance).
4. Enhancing the inspectorate and laboratory functions.
5. Providing strict penalties to prevent or reduce the excesses and misuse of the systems in the public and private sectors.
6. Improving purchasing of drugs.

### 6.1.3 Drug Legislations and Regulations in State of Kuwait

The interview results indicate that there are a number of areas of concern with the Drug Legislations and Regulations of the Health Care System in Kuwait, these include:

1. Issues with the Drug Registration and Licensing Process in the Drug and Food Control Administration.
2. Limits of authorization and power for the Quality Assurance Department in Drug and Food Control Administration .
3. Weakness in the penalties given out for irregularities in carrying out the regulations in private pharmacies, hospitals, health clinics, medical stores, medical companies, local agencies and pharmaceutical industries.
4. High price range of medications in the private sector where price controls should operate.
5. Limitation in the adherence of the legislation control of pharmaceuticals in both the public and private sectors.

6. Poor use of Pharmaco-economics controls in providing drug cost effectiveness expertise in public sector.

In introducing the NDP, the KMOH should look closely at the present Regulations and Legislation and possibly look at a major overhaul of the current rules, guidelines and legislation and consider how these areas can be better controlled. With the introduction of an Essential Medicines Programme, the present rules on medicines procurement and access will need to be reconsidered and the necessary legislation put into place. The legislation should be broad in its scope in order to address all the main problems and be flexible enough to make the legislation specific to difficult areas.

Therefore the drafting or revising of current Drug Regulations and Legislation should be a priority in both the drafting of the NDP and in the work that follows. This can be done by making a full inventory of existing laws and regulations, and carefully deciding what type of Legislation is required. Then, legal experts (from Kuwaiti Government) should collaborate closely with health professionals (KMOH) and other stakeholders in drafting the new text to ensure that all drafted Legislations do not conflict with the States laws. After drafting, a wide consultative process is needed to inform interested parties (Private sector, Pharmaceutical Association, Medical Association and Kuwait University) and to enable them to comment and express their concerns. At this time it is important to ensure that there is political support for the proposed changes and that this support is maintained throughout the process.

When writing the law, the practicalities of future enforcement should be kept in mind. In addition if there are no strategies, facilities and resources for implementation and enforcement, legislation on its own is likely to achieve negative results. In carrying through these discussions and drafting of policy it is important to balance the aims and objectives to ensure that that these can be properly enforced and not to be too ambitious by introducing policy that cannot be implemented and enforced. (WHO, 2001)

The following are a listing of areas and There are some suggestions (listed below) can be useful to support KMOH in development , updating and revising the existing drug Legislations and Regulations in Kuwait, includes:

1. Overall to improve the enforcement and strengthen procedures (seizures), penal provisions and administrative penalties, for areas of the current Legislation and Regulation in the Health and Pharmaceutical field.
2. Issuing adjusted and improved Legislations and Regulations for establishment of;

a). Management Organisation relating to the quality of pharmaceutical services in the

CMS Administration and public hospitals.

b). Develop and introduce and Essential Medicines List for use in the procurement

system.

c). Develop and introduce a Pharmacovigilance Center in the State.

d). Under the heading of an EML to establish a Medicines Cost Effectiveness

Department in the CMS Administration.

e). To establish an Electronic link system throughout the public health areas in Kuwait.

f). To bring all this together under a Pharmaceutical and Health Services NDP and efficiently introduce this NDP in Kuwait.

3. To provide and strengthen authorization and power for the QA Department of Drug and Food Control Administration to ensure enough control and ability to monitor drug registration, testing and licensing.

4. Strengthen penalties to encourage the private sector to reduce irregularities in the health field.

5. Development the requirements which requires a certain level of academic attainment and attendance at training programs for public health professionals.

6. Overall the KMOH should work towards reviewing and updating most of the health and Drug/Medicines Legislations and Regulations because the majority of the Legislation and Regulations were issued in the eighties and nineties of last century, where they were created in accordance with conditions and needs of that period and before the conflicts in Kuwait.

### 6.2 Weaknesses in the Drug Registration system in Kuwait

Drug Regulation covers various areas, to include estimation of the quality, safety and effectiveness of a drug, compliance of manufacturers/suppliers through the processes relating to GMP standards i.e. good manufacturing standards, pre marketing evaluation, thorough examination of various stages of drug supply chain. Drug regulation activities also include maintaining the register of available medicines and their post marketing survey results. For medicines currently it involves undertaking random sampling for quality checks and controls and pharmacovigilance reporting of registered drugs (DFID, 2004).

Registration of Drugs/Medicines is an important component of drug regulation. Drug Registration is the interaction and a relationship between the various parties involved in pharmaceutical sector. It can form a bridge between Legislations and the Sciences or it connects the pharmaceutical manufacturers with the regulatory authorities along with allowing comments and inputs from the medical professionals and the patients. The Regulatory Authority is also interconnected with many other authorities in the MOH and other protection agencies and law enforcement agencies, such as the customs authority. When discussing Drug

registration is however an overarching terminology for a groups of administrations and includes product licensing or marketing authorization, medicines inspection and quality assurance (Boxtel et al., 2008).

In addition, the Drug Registration Authority can undertake various advertisements for promoting and disseminating drug information. Dependent on the origins of the medicine the drug registration process can involve various steps including the medicine/drug evaluation and consideration of pharmaceutical quality data, evaluation of; animal preclinical toxicology studies, human clinical trials and product information documents (DFID, 2004).

During the fieldwork for this PhD research study, the main issues found in the Drug Registration System during informal visits to this Administration (in 2014, Chapter 5) and structured discussions with many of the senior management staff (in Chapter4), were; absence of training of staff in stability, clinical, bioequivalence and GMP studies and other issues were mentioned in Chapter 5.

Based on this information, it is clear that the Registration of Drugs/Medicines in Kuwait suffers from a number of weakness and it is proposed that the KMOH should concerned about these present issues because drug registration is such a necessary operation for developing health services in Kuwait. The following section discusses the importance of Drug Registration and its affects on Health Care System.

### 6.2.1 Importance of Drug Registration

Drugs are complicated chemical substances whose effect cannot be determined by a ordinary consumer therefore it is important in a well organised health system to make the consumers aware of information to help them understand both the value and the side effects of the medicines and to take the correct decision on matters

relating to which medicines to use, how to use them, when to use and to consider the positive benefit against the side effects of the drugs as no medicine can be regarded as completely safe for human health. Drug Registration is required to determine the secure drug for consumption but due to complexity of compounds even healthcare professionals are not fully informed and safe decisions on possible effects of the drug without having been well trained in studies of drug registration. As an example; clinical pharmacology involves the most complicated clinical aspects of medicinal quality, effectiveness and safety. For this the training program in clinical, stability, GMP and bioequivalence studies is necessary for staff of Pharmaceutical, Veterinary, Food Supplements, Cosmetic and Herbal Registration departments in Kuwait because they normally approve the final licences for imported and manufactured medicines for both the public and private sectors and they provide the final clearance on quality and safety of a medicine before it reaches the patient (Boxtel et al., 2008).

In addition, the scientific matters related to medicines are very sensitive as consumption of inappropriate, poor quality; harmful or adverse drugs can cause therapeutic failure, exaggeration of illness, insensitiveness to drugs or even death so normal medical trainings are not sufficient to understand the correct nature of drug and its effects to ensure safety. Failure to fulfil the responsibility in regard to the medicines quality and safety can result in lowering of the faith in the health system, and in the health professionals and manufacturers and distributors of medicines. It can tragically lead to loss of life as well as wealth both for the consumers and also for the manufacturers and government, and for this reason it is the duty of the KMOH to work for safeguarding the health and safety of its population in Kuwait by development and improvement the drug registration system (Boxtel et al., 2008)

### 6.2.2 Development of Drug Registration System in Kuwait

The overall conclusion from these studies are that the KMOH should re-examine the registration of drugs policy to regain benefits in ensuring high quality and safe medications for use of its population and should follow these steps:

1. Provide staff needs of training programs specifically in stability, GMP, clinical and bioequivalence studies.
2. Update the list of required procedures and standards for registration of drugs/medicines and medical devices.
3. Establish an e-link system between the Supervision of Pharmaceutical Registration and Release and Supervision of Laboratories to develop a more appropriate chain of authority to ensure that medicines release is based upon the correct basis of medicines quality and safety.
4. Increase the co-operation with other local or international agencies to ensure availability of recent and appropriate data for the drug and its quality and safety profile.
5. Provide a drug index system from the Drug and Food Control Administration which would act as a reference for interested persons and agencies.

### 6.3 The need to strengthen penalties, in order to restrain the spread of counterfeit and unregistered drugs in the Kuwait medicines market.

The majority of interviewees (82.6%) of the 121 (in Chapter 4) indicated that Kuwait has weakness in the Health Care System for sanctioning and endorsing penalties for wrong doing in terms of the legislation and regulation of medicines. It was indicated by the interviewees that in a number of areas it does not carry through the penalties or they are of a low level against the infringements incurred. The specific area mentioned were; for irregularities in the private sector, limited control over the pharmaceutical processes (44.6% of the interviewees mentioned this); establishment of private pharmacies and warehouses without a license from the MOH or obtained through an incorrect procedure, in addition, violation of advertising, and promotion decisions of the pharmaceutical products, is insufficient and 46.3% of the interviewees suggested that there is an issue with access to

quality, safe and efficacious medicines especially in the private sector due to presence of purchasing of unlicensed and counterfeited drugs in some private pharmacies.

For these reasons, the interviewees clearly recommended to strengthen the control especially over the private pharmacies to prevent any illegal trading in medicines and to strengthen the penalties for this trading (e.g. the purchasing of non-prescribed, unlicensed and counterfeiting drugs) to reduce this matter.

Medicines which are considered counterfeit are also an increasing area of concern in Kuwait and this violation was mentioned by many of the interviewees and during informal visits to the Administrations. Counterfeit medicines are a worldwide problem, which has recently attracted a large attention from the major Drug Regulatory Agencies, Governments, WHO and National and International Police Organisations (including Interpol). Counterfeiting is a large business with known international criminal gangs involved. At this time, when a NDP is likely to be developed in Kuwait it is a good time to include the protection against counterfeiting in Kuwait. To understand the problem more clearly the definition of counterfeiting of drugs/medicines is given below, with some recommendations from with the world groups and agencies, including the WHO and an indication of where counterfeiting occurs, how to combat it and how the penalties for counterfeiting medicines can be strengthened.

### 6.3.1 Definition of Drug Counterfeiting

Drug counterfeiting refers to the bogus medicines, which can be polluted or may contain the wrong ingredient, poor quality ingredients or contains no active component. Counterfeit medicines may even contain the correct active ingredients but not in correct dosage. These drugs are hazardous to health and their marketing is considered as illegal (WHO, 2012).

According to the USA Food and Drug Administration (FDA), Counterfeit medicines may be contaminated, may not contain the benefits for which the drug is intended to be prescribed, or may be packaged in spurious packaging. Use of such improper medicines may not cure the disease or ailment and can even lead to dangerous side effects (FDA, 2009).

Furthermore problems of drug counterfeiting is not just limited to one nation, it is a serious global concern as in some countries it was projected that about 30-50% of medicines provided to treat hazardous diseases are counterfeit. However it is difficult to obtain an accurate estimate of the extent of medicines counterfeiting. It is proposed that more efficient and more intense research is required to explore the basis of the problem and to gauge the harm it is causing (Margaret, 2010). Figure 6.1 shows examples of spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines (WHO, 2010).

| SFFC medicine | Country/Year | Report |
|---|---|---|
| Anti-diabetic traditional medicine (used to lower blood sugar) | China, 2009 | Contained six times the normal dose of glibenclamide (two people died, nine people hospitalized)[1] |
| Metakelfin (antimalarial) | United Republic of Tanzania, 2009 | Discovered in 40 pharmacies: lacked sufficient active ingredient[2] |
| Viagra & Cialis (for erectile dysfunction) | Thailand, 2008 | Smuggled into Thailand from an unknown source in an unknown country[3] |
| Xenical (for fighting obesity) | United States of America, 2007 | Contained no active ingredient and sold via Internet sites operated outside the USA[4] |
| Zyprexa (for treating bipolar disorder and schizophrenia) | United Kingdom, 2007 | Detected in the legal supply chain: lacked sufficient active ingredient[5] |
| Lipitor (for lowering cholesterol) | United Kingdom, 2006 | Detected in the legal supply chain: lacked sufficient active ingredient[6] |

**Figure 6.1 Examples of spurious/falsely-labeled/ falsified/counterfeit (SFFC) medicines. (WHO, 2010)**

### 6.3.2 The WHO and International Organization's Recommendations

The WHO during the World Health Authorities Meeting were asked to become more involved in coordinating national and regional support for controlling medicines counterfeiting (WHO, 2010). As a result the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was developed by the WHO and International Regulatory Authorities (and with the major pharmaceutical companies) to help countries in protecting against counterfeiting drugs, in 2006. The IMPACT initiative has worked towards involving a large number of stakeholders in concerted efforts for protecting the public from purchasing and consuming SFFC drugs. IMPACT's areas of focus particularly centred on preventing the manufacturing and marketing of counterfeiting medicines, through the development of improved legislative and regulatory infrastructures, and improved and monitored regulatory execution of policy measures and their effective enforcement, by making use of the latest available technology and working towards a consistent approach for information sharing and efficient communication through worldwide publishing (WHO, 2010). In addition many Regulatory Agencies and the Pharmaceutical Companies are working together and with scientists to detect and stop medicines counterfeiting.

These developments together with International Conferences and publications by the WHO are starting to have an impact through promotion prevention of counterfeiting and awareness creation by way of the Conferences/ Symposia and through documentation from the major Drug Regulatory Authorities, WHO and Pharmaceutical Companies. This spread of awareness among decision makers, health professionals and consumers, and also development of global inspection by the medicines inspectors of the regulatory agencies and the development of an alert system, the assembly and circulation of reliable and quality data has had an effect on reducing the level of SFFC drugs in public circulation.

For Kuwait, the absence of a more controlled Pharmaceutical Sector has led to a considerable problem in terms of circulating counterfeit medicines. Part of the reason for this is the limited control on incoming medicines particularly in the Private Sector.

However with a NDP in place in Kuwait and the tightening of the medicines quality and testing regimen in terms of decision on the requirements for testing, setting of standards for QA and GMP, emphasizing the need for bioequivalence checks and better checks on inter-changeability of medicines, there is likely to be greater control over the appearance of counterfeit medicines. In addition there may be proposals to examine the place of bio-similarity in medicines and tightening of certificates for medical products.

As indicated above the WHO, the major Drug Regulatory Agencies, Pharmaceutical Companies, University Researchers and Instrument companies continue to provide information and more specific technical support to countries (specifically developing countries), helping in review of national regulatory authorities for making them more effective in combating medicines counterfeiting. As an example the WHO have publications which provide IT assistance in developing quality, safety and pharmacovigilance based systems, and can provide quality WHO standards for medicine testing in quality-control laboratories (WHO, 2011).

Based on the information presented above, it is suggested that the KMOH should become more aware of the international developments in preventing drug counterfeiting and through the presence in the future of a NDP should review the literature and recent publication in this area and take knowledge from the benefits reported from the WHO and International Organizations (particularly the USA, FDA and the EMA in the EU) from their recommendations, experiences and suggestions. It is also considered important that more interaction is encouraged with the agencies and through attendance of the appropriate worldwide

conferences and symposia which either concentrate on reducing medicines counterfeiting or have a large section of discussion on the subject (e.g. International Conference on Drug Regulatory Affairs [IFPMA]) and the KMOH could send a group of Regulatory Pharmacists from the DFC to attend these conferences and training courses which concentrate of reducing the impact of medicines counterfeiting

### 6.3.3 Examples of successful strengthening of penalties for purchasing of counterfeit and unregistered drugs.

Therefore counterfeit and unregistered drugs pose a significant threat to the health of the public. Patients may often be unaware that they are purchasing counterfeit drugs, and they can be unaware of the risks that these pose to their health. There are a number of reasons why a patient may inadvertently buy a counterfeit medication from self-medication through to cost because they may not believe that their condition warrants full medical attention (Shabsigh *et al*, 2004).

An example of a commonly counterfeited drug is; Phosphodiesterase type 5 inhibitor (PDE5i) which is used in the treatment of erectile dysfunction, counterfeit sellers offer illegal access to the drug because the patient may want to avoid healthcare professionals due to the shyness and misconceptions associated with erectile dysfunction (Dorsey and Hellstrom, 2011).

The WHO estimated in 2006 that less than 1% of pharmaceutical sales were estimated to be counterfeit medications in developed countries that come under the established regulatory lists (WHO, 2006). Although this may not seem like a significant number, 1% roughly can equate to over 8 million packs of counterfeit medicines, which are worth in excess of £425 million (Clark, 2008). In addition the level of counterfeiting has increased since that year.

In the early years there was the misconception that medicines counterfeiting was a problem mainly confined to developing countries, because of their lower intensity of the regulatory confines. However this was quickly dispelled and the level of counterfeit medicines reaching the population across most countries is relatively high. The reasons for the increase are; the market forces of access to medicines without a doctor's visit, use of medicines outside the normal health related practice (e.g. steroids in body building and for performance enhancing athletic use). In some cases where there may be inadequate access to medications within the healthcare system, for example in rural areas where medical centres are often distant from the patient. The health effects of taking these product can be considerable as can be shown by the death of a 58 year old Canadian woman who died after she ingested counterfeit medication in 2006 where biochemical analyst experts found high levels of metals in her liver, including aluminum and exceptionally high levels of phosphorus, titanium, tin, arsenic and others. These medicines were bought from an eastern European website (Solomon, 2007).

There are however in recent years many examples of successful legislation being developed in the European Union which was aimed at improving patient safety and reducing counterfeit medication contamination of medicine supply chains. One such section of legislation was introduced in 2011, where the EU adopted a directive on counterfeit drugs, and gave European Countries 18 months to implement the changes shown in the legislation (Taylor, 2011). Alongside this the packaging was changed and three additional features were added to the packs to ensure that they are recognized as legitimate, these includes; the addition of a barcode, authenticity feature and seals designed to prevent any tampering (European Commission, 2008).

Alongside the packing improvements some countries introduced stiffer fines and penalties In the UK enhanced penalties were introduced, which were welcomed at a number of levels (Jackson, 2010), and for criminally counterfeiting medications in the UK the perpetrators could face up to a 12 year prison sentence (Nature Medicine, 2010). Also the MHRA was given the capacity and ability to prosecute

the manufacturers and distributors of counterfeit and unregistered medications in the UK and therefore they are working with law enforcement to do this (MHRA, 2010).

In terms of overall rights to import and sell medicines in the UK, the law allows individuals to import pharmaceutical products for personal use provided they hold a license within the country of origin and this includes products which can be bought over the internet (Hill, 2005).

As time has passed the skills of the counterfeiters has increased and the quality of the packaging for medicinal products can be very similar to the original package. Figure 6.2 below is an example of this, where the packaging can be difficult to distinguish from an authentic sample. The counterfeit sample in this case should be a growth hormone used in AIDS treatment. However the counterfeit product contains no active ingredient (FDA, 2009).


**Figure 6.2 Counterfeit Serotism 6mg (adopted from FDA, 2009).**

As another example of how penalties were introduced and increased for medicines counterfeiting in this decade is the law on drug counterfeiting which was changed in the Ukraine (2011), where the law established a liability for the falsification of drugs. The changes ensured that any production, purchase, transport, storing or in fact possession with any intent to sell the medication or selling counterfeit drugs can be punishable by a prison sentence ranging between three and five years. If these actions would then be repeated, or would result in injury or damage to health of any person, the prison sentence increases from between five and eight years. If the actions would cause death, this would lead to serious consequences or if it were performed on a massively large scale the person(s) concerned could either face between eight and ten years imprisonment or alternatively a life sentence (Mondaq, 2012).

Based on the information presented above, it can be indicated that the KMOH should be aware and take note of the developments in trying to reduce medicines counterfeiting and move towards introducing clear legislation and penalties by studying, the successful examples of these countries and strengthening of penalties for purchasing of counterfeit and unregistered drugs to ensure access of quality, safe and efficacious drugs for the population of Kuwait.

### 6.3.4 Spread of drug counterfeiting in State of Kuwait

The level of possible drug counterfeiting in Private Pharmacies in Kuwait over recent years has been measured under the heading of (Number of irregularities for private sector in 2013) by the Drug Inspection Administration during the fieldwork for this PhD research study. From informal discussions with the Medicines Inspectors, it can be indicated that there appears to have been a relatively large spread of counterfeited and unregistered drugs in the pharmacies which suggests that these may be readily available in the medicines market in Kuwait. The Table 6.1 shows the number of large irregularities at the private pharmacies (in all governorates of the country) that have been monitored by Department of Private

Inspection during morning inspection period in 2013. Based on the information presented in a table below, it can be observed that the private large irregularities (specifically sale of unregistered and counterfeited drugs in private pharmacies in Kuwait) were 94 cases (KMOH, 2013 d)

**Table 6.1 Number of large irregularities of the private pharmacies in Kuwait during the morning inspection period in 2013 (KMOH, 2013 d)**

| Month/ Governorate | Hawali | Al Ahmadi | Al Farwaniah | Al Asimah (Cabital) | Al Jahra | Total Irregularities Per Month |
|---|---|---|---|---|---|---|
| **January** | 3 | 2 | 4 | 3 | - | 12 |
| **February** | 2 | 2 | 1 | 1 | - | 6 |
| **March** | 1 | 3 | 3 | 1 | - | 8 |
| **April** | 1 | 1 | 3 | 1 | 1 | 7 |
| **May** | 2 | - | - | - | 1 | 3 |
| **June** | 3 | 1 | - | - | 4 | 8 |
| **July** | 2 | - | 1 | - | - | 3 |
| **August** | 5 | 2 | 5 | 2 | - | 14 |
| **September** | 5 | 2 | 2 | - | 3 | 12 |
| **October** | 5 | 2 | 1 | - | - | 8 |
| **November** | 2 | 1 | - | 1 | - | 4 |
| **December** | 3 | 2 | 3 | 1 | - | 9 |
| **Total** | **34** | **18** | **23** | **10** | **9** | **94** |

In addition, the number of large irregularities of the private pharmacies that have been monitored by Department of Private Inspection during night inspection period in 2013 reached to 114 irregularities (related to sale of unregistered and counterfeited drugs in private pharmacy in Kuwait), and it can be observed that

there is a spread of counterfeit and unregistered drugs in the market. . See table 6.2 (KMOH, 2013 e).

**Table 6.2 Number of large irregularities of the private pharmacies in Kuwait during night inspection period in 2013 (KMOH, 2013 e)**

| Month/ Governorate | Hawali | Al Ahmadi | Al Farwaniah | Al Asimah (Cabital) | Al Jahra | Total Irregularities Per Month |
|---|---|---|---|---|---|---|
| **January** | 3 | - | 1 | 1 | 1 | 6 |
| **February** | 2 | - | 2 | - | 1 | 5 |
| **March** | - | - | 1 | 1 | - | 2 |
| **April** | 1 | 1 | - | 2 | - | 4 |
| **May** | 6 | 2 | 5 | 3 | 2 | 18 |
| **June** | - | 1 | - | - | 2 | 3 |
| **July** | 1 | - | 1 | 2 | - | 4 |
| **August** | 1 | 1 | 1 | - | 1 | 4 |
| **September** | 5 | - | 3 | 1 | - | 9 |
| **October** | 8 | 2 | 8 | 2 | - | 20 |
| **November** | 7 | 3 | 9 | 2 | 2 | 23 |
| **December** | 5 | 2 | 7 | 1 | 1 | 16 |
| **Total** | **39** | **12** | **38** | **15** | **10** | **114** |

Based on the information presented above (Tables 6.1 and 6.2), it can be indicated that there is a spread of counterfeited and unlicensed drugs in private market in Kuwait because the total number of private irregularities in 2013 (in both morning and night inspection period) were 208 large irregularities and when compared that number with a number of private pharmacies (450 private pharmacies) in Kuwait, it can be observed that there is a serious issue in this aspect.

In addition, during the fieldwork for this PhD research study (in 2014) the author had several visits to the seizures store of the Drug Inspection Administration, and based on the figures (photos taken of the seizures during the fieldwork visit) below it can be observed the large number of confiscated drugs (counterfeited and unlicensed drugs) from the private pharmacies in 2014.


**Figure 6.3**

The figure above shows a number of confiscated drugs which includes; counterfeited and unregistered drugs by the inspectors of Drug Inspection Administration in 2014.


**Figure 6.4**

The figure above shows, the confiscation of slimming products, which, are unregistered from KMOH and were purchased in the private pharmacies in Kuwait in 2014.


**Figure 6.5**

The Figure above shows, the type of confiscated counterfeited drugs which includes; herbal, sexual, food supplement and pharmaceutical products in the seizures store of the Drug Inspection Administration in 2014.


**Figure 6.6**

The Figure above shows the comparison between confiscations of counterfeiting drugs and the authentic copies such as; Augmantin, Sildenafil, Plavix and Zyprexa (the authentic and the counterfeit drugs side by side).

6.3.5 Main solutions which have been suggested to stop drug counterfeiting

The scientists and academics/companies working in pharmaceutical analysis have been working on finding solutions to the identifying of counterfeit medicines for some years and there is some highly sophisticate instrumental methods to handle the problem. Some is in the form of successful technology, procedures and training programs. These could be appropriate to support the KMOH in increasing and promoting the ability to control the spread of counterfeited drugs in the private

sector by providing it to the health professionals staff (inspectors). Some of these include:

1. The Molecular Pharmaceutical Authentication using Energy Dispersive X-Ray Diffraction (EDXRD) Technology: where the low quality or counterfeiting drugs can be detected using EDXRD even when they are inside sealed packing, without a technical staff requirement. In addition, the XT250 System promptly correlates drug's molecular crystalline structure against its standard profile to decide its authenticity and quality. This test is suggested to just take a few minutes to classify the drug into counterfeiting or not. (Adams, 2012)

2. The application of standard procedures for drug inspectors from the Drug Inspection Administration: by provide the specific guidelines to the inspecting officer about the drug documents to be investigated, sampling methods, method to seal the sample to ensure it remains undisturbed until it reaches the quality control lab, separating suspected drugs and stopping their further distribution, to encourage recording of actions taken and seizure and elimination of counterfeiting drugs (Khalen, 2012).

3. The introduction of appropriate training programs related to counterfeit drugs for inspectors: Special training can be provided to inspectors of the Drug Inspection Administration to provide support in identifying the possibility of counterfeiting in a particular drug. In addition, the USA, FDA has been updating the information about many drugs on its website. With the use of such information both the health professionals (pharmacists and physicians in Kuwait) and patients should be conscious while taking drugs of the side effects or if the drug appears or tastes differently or is packaged in a different way or the drugs are damaged or cracked. In these cases it may be found to be a counterfeit drug (Hassett, 2012).

The overall conclusions from the studies above suggests that it may be necessary for the KMOH to carry out development and improvement of control over the pharmaceutical process in the private market based on the information presented in this section. However from experience there are problems in private pharmacies in Kuwait. But it can be suggested that these can be alleviated by the KMOH introducing legislation, inspections and testing methods. With these it becomes possible to resolve the issues surrounding the purchase of unlicensed and counterfeited medicines in private pharmacies in Kuwait. The action which could be taken includes:

1. Strengthening penalties (as presented in Chapter 5), in order to restrain the spread of counterfeit and unregistered drugs in the market and to solve weakness of other aspects (as mentioned below). Because the present penalties are insufficient and inappropriate to reduces the issues in this area. The trade penalties for the private sector in Kuwait could include the following punishment levels:

a). There could be punished by imprisonment for a period not exceeding two years or a fine not exceeding two thousands KD (7000 USD) or by both of them if:

- There is a violation of drug pricing decisions.
- The licensed premises are used for other purposes.

b). There could be punished by fine not exceeding two thousands KD (7000 USD) if:

- There is violation of advertising and promotion decisions of the pharmaceutical products.

c). There could be punished by giving a warning, suspension from working for a period not to exceed one year, cancellation of the license to practice the profession, closure of the premises not exceeding six months if:

- There is violation of the rules regulating the registration process of the pharmaceutical products and the medical devices.

- The private pharmacy sale of any pharmaceutical product is not from a source which is a registered local agency in Kuwait.

- Sale of any pharmaceutical product which is not-registered in a Kuwaiti Drug Control Administration for the private market.

- The private pharmacy, companies and stores Sale of any counterfeited drugs.

Based on the trade penalties for the private sector in Kuwait presented above, it is suggested that the KMOH strengthen those penalties because of what can be classed as greed of some operators of private pharmacies, suppliers and companies taking advantages of weakness of the present penalties and they do not care if they have to pay modest penalties when compared with their great profits. The KMOH will however have to arrange the following:

1. Provide enough technologies, procedures and training courses in counterfeiting drugs for inspectors of the Drug Inspection Administration.
2. Increase cooperation with the Ministry of the Interior and Kuwait General Administration of Customs to ensure enough control over border crossing centres at Kuwait International Airport and sea and lands ports.
3. Provide an e-link system between Drug Inspection Administration and Drug and Food Control Administration to ensure continuity access to all a necessary data (update licensed and registered drugs and approved advertisements) at the right time, which supports inspectors of Department of Private Inspection to monitor traded drugs in private pharmacies.
4. Increase the cooperation and gain support from agencies such as the; WHO, MHRA, FDA and European Commission and take the benefits from their recommendation, experiences and suggestions.

5. Increase the educational and awareness programs for the public by using media, leaflets and publishing to ensure raising awareness about the dangers of using counterfeiting drugs.

Finally it is accepted that counterfeit and unregistered drugs pose a problem and despite this, the laws controlling these are considered to be lax. There is therefore a need to strengthen the legislation in Kuwait within the NDP to protect the population of the country and ensure that they are not subjected to any adverse effects that the ingestion of a counterfeit drug may cause.

### 6.4 High price range of medications in the private sector and lack of a Drug Cost Effectiveness Department in State of Kuwait

Another aspect for consideration in the NDP under the Drug and Food Control Administration is medicines pricing and according to the structured interview results [Chapter 4, in question 6: (Do you think that the price range of medication in the private sector is publically acceptable?)], it was found that 51.2% of those interviewed did not accept that the price range of medicines in the private sector was acceptable and they suggested that the range in the private sector was exaggerated when compared to the Kingdom of Saudi Arabia (KSA). In addition they suggested that the Drug Pricing Department of the Drug and Food Control Administration is not strict enough with the drug prices in the private sector, due to a lack of a Drug Cost Effectiveness Policy and having applications, experts and processes to measure this in the KMOH.

Based on this information, it is suggested that the Pricing Department should firstly collect further information and discuss the results to ensure they are using the correct assumptions from the collected data of this study(interview and KMOH data), from this and the solution suggested below it becomes possible to accurately

identify the main issues, solutions and future action plans of resolving the perceived high price range of medications in the private sector in Kuwait . The information which will be further examined here includes:

- Definition of drug cost effectiveness.
- How to choose cost effectiveness of drugs, injections and medical devices.
- Cost and price range of drugs in Kuwait.

### 6.4.1 Definition of drug cost effectiveness

Drug cost-effectiveness can be determined by analyzing the economic competence and effectiveness of one or more forms of the drugs in the medicinal form. In addition it involves making a decision of whether one drug against another is as clinically effective and has a lower cost against another. A relatively easy decision is taken when one drug provides more benefit at the same or lower cost, or lower cost for the same or larger benefit (David Parkin, 2009).

Cost-effectiveness analysis normally compares the money involved alongside the health benefits by measuring the level to which it can be considered as delivering value for money. It is proposed that this helps the decision makers to efficiently and effectively use the often limited healthcare resources (Ceri Phillips, 2009). Also the decision process in a larger study with involvement of a cost-effectiveness unit such as National Institute for Health and Clinical Excellence,(NICE) in the UK it becomes an economic study design in which the results from various alternative drugs are deliberated by means of a single outcome generally in units like life-years achieved, deaths avoided or cases identified. Substitute choices of drugs are then evaluated with cost per unit of effectiveness, NICE, (2008).

### 6.4.2 How to decide upon cost effectiveness of drugs, injections and medical devices

In order to determine the cost effectiveness of one or more drugs, medical devices and injections, it is proposed that firstly the nature of their combination or comparison should be defined whether they are independent or mutually exclusive. They are treated as completely independent when the money involved and effects of one drug/device under consideration are not impacted by the introduction or otherwise of other drug/device. This occurs when introducing one drug/device leads to clinical restriction on the other drug/device implementation, or where the introduction of one drug/device results in variations to the costs and effects of another. In these cases they are considered as mutually exclusive.

In order to measure the effectiveness a cost-effectiveness ratio (CER) can be used and should be linked to the amount in the budget to find out the most cost-effective strategies. In a CER costs are measured in monetary terms while benefits in terms other than money. For Independent programs Cost effective ratio (CER) is calculated as: choice is made for Lower CER (Ceri Phillips, 2009).

Other factors which also should be considered for determining the most cost effective strategies are sensitivity analysis; issues of equity, needs and priorities. Accurate Interpretation of these ratios is an integral part of the decision making process to arrive at accurate and reliable conclusions; assumptions and perspective of the study should be stated clearly for effective outcomes (Ceri Phillips, 2009).

In addition, purchasing of generic drugs instead of patented drugs help in reducing the cost of the drugs. Generic medicines are pharmaceutical products which have the characteristics of originator compound so can be replaced in place of source compound. These are sold once the original patent or other exclusivity rights

expire, then they are manufactured by a new company who obtain a Generic license (The World Medicines Situation, 2004).

In addition, the entry of generic products and competition among them helps in making available the lowest priced generic medicines for the developing countries (WHO, 2010).

### 6.4.3 Cost and price range of drugs in Kuwait

During the fieldwork for this PhD research study (2012–2015), the author had several informal visits to Drug Pricing Department and CMS Administration and based on the structured discussions with staff involved (Chapter 4) and the collected data (mentioned below) from these areas, it can be observed that the price range of drugs in the private sector is considered to be very high when compared to KSA. This is despite the fact that the two countries are adjacent and the sources of imported drugs and tariffs on imported drugs are similar (5%). Table 6.3 below shows the comparison in prices for the same drugs in private market between Kuwait and KSA in 2015 (KMOH, 2015 j).

**Table 6.3 Comparison in prices of the same drugs in private market between Kuwait and KSA in 2015 (KMOH, 2015 j)**

| Name of Drug | Price of drug in Kuwait ($) per packet | Price of drug in KSA ($) per packet |
|---|---|---|
| **Arcoxia 90 mg (28 tablets)** | 105 | 49 |
| **Lercadip 10 mg (30 tablets)** | 38 | 16 |
| **Ezetrol 10 mg (28 tablets)** | 100 | 60 |
| **Plavix 75 mg (28 tablets)** | 82 | 66 |
| **Januvia 100 mg (28 tablets)** | 97 | 37 |
| **Zocor 20 mg (28 tablets)** | 82 | 32 |
| **Clasid 500 mg (20 tablets)** | 40 | 24 |
| **Clasid XL 500 mg (7 tablets)** | 18 | 11 |

Based on the information presented in the table above, it can be observed that there are large differences in drug prices between the costs in the private market in Kuwait and KSA. In some cases the difference is as high as double and sometimes triple the price in KSA. What are the reasons for these high prices? The investigation suggests it may be caused because of two main reasons includes;

a). The absence of a Drug Cost Effectiveness Department in the Drug and Food Control Administration, and in addition, possibly poor drug cost effectiveness monitoring because of deficient; training programs and appropriate staff) in the Drug Pricing Department. It was found that the staff responsible for pricing of medicines may need more experience and training in this aspect to ensure that they have access to appropriate prices for the consumers and private suppliers, companies and pharmacies.

b). Absence of an Essential Medicine List, where the current situation doesn't help the public and private sectors in determining the needs of appropriate medicines and the selection of these medicines for supply in the long term.

Based on the information above, it is suggested that the KMOH can control and where appropriate reduce the prices of medicines in the private sector by introducing:

1. A medicines cost effectiveness programs and special training for the staff of the Drug Pricing Department of the Drug and Food Control Administration.
2. Formation of a multidisciplinary Pricing Committee, which can ensure a transparent pricing structure and the pricing system, should not distinguish between public and private sector.
3. Replacement of wholesale and retail mark-ups with a fixed professional fee.

4. Formation of a price monitoring system with contrasting drug prices to international levels.
5. Regulation of the effects of inflation on drug prices, and the provision of priority medicines to the private sector (Loraine Hawkins, 2011).

In summary, it was observed that there is an absence of a Drug Cost Effectiveness Department in the administrative formation of a CMS Administration, and this absence of this important department effects negatively on the process of purchasing of medicines and may not allow optimum price levels to be achieved to obtain the appropriate drugs at suitable prices and cause overcharging for the State budget, which could otherwise be used in other areas of the MOH.. Furthermore according to the discussions with senior staff in the CMS Administration (Chapter 6) it was noted that the method used in determining the prices of purchased medicines was only based on the experience of the senior staff without consulting any experts of cost effectiveness.

Based on the information presented above, it is clear that there are problems in the process of pricing drugs in the CMS and it is important as part of the NDP to establish a Drug Cost Effectiveness Department for this Administration, to advise on drug pricing. It is also suggested that the KMOH should take into account the need to develop the process of drug pricing. But they should also be aware that in reducing medicines costs in the private sector there should be no negative effects on the patient's health.

As an overall conclusion from these studies, it can be suggested that the KMOH should develop the process of purchasing drugs at suitable prices in a more measured way and save the national budget by carrying out the following;

1. Establishing a Drug Cost Effectiveness Department in the CMS Administration.

2. Increase the cooperation with the Gulf Cooperation Council (GCC) countries in the field of purchasing of medicines requirements by a collectively tender process to obtain lowest costs. Such cooperation could lead to economies of scale.
3. Purchasing of generic drugs where available instead of patented drugs, as patented drugs have a negative impact on the state's budget and this is due normally to their high prices and the manufacturer's monopoly. The Table below shows the typical difference in cost between patent drugs and generic drugs which the KMOH purchased in 20012-2013.

**Table 6.4 The difference in cost between patent drugs and generic drugs which the KMOH purchased in 20012-2013 (KMOH, 2013 f)**

| Medical Group | Patented Drugs<br>( price per unit )<br>$ | Generic Drugs<br>( Price per unit )<br>$ |
|---|---|---|
| **Domperidone**<br>**(10MG) Tablet** | Motilium<br>(Janssen , Belgium)<br>0.098 $ | Pokinin<br>(Jamjoom , KSA )<br>0.077 $ |
| **Diclofenac Potassium**<br>**(50 MG) Tablet** | Cataflam<br>(Novartis , Switzerland )<br>0.14 $ | Rapidas<br>(Tabuk , KSA )<br>0.071 $ |
| **Atenolol**<br>**(100 MG) Tablet** | Tenormin<br>(Astrazeneca , Sweden )<br>0.08 $ | Apoatenol<br>(Apotex INC , Canada )<br>0.0274 $ |
| **Metformin**<br>**(500MG) Tablet** | Glucophage<br>(Merck Sante , Germany )<br>0.042 $ | Metaphage<br>(KSPICO , Kuwait )<br>0.0105 $ |
| **Amoxicillin+Ciavulanic**<br>**(1GM) Tablet** | Augmentin<br>(Glaxo Smith Kline , UK )<br>1.033 $ | Klavox<br>( SPIMACO , KSA)<br>0.1693 $ |

The overall conclusion from these studies, indicate that the high price range of medications in the private sector and lack of a Drug Cost Effectiveness Department in State of Kuwait are main issues and the KMOH could carry out the solutions for these aspects to ensure the availability and affordability of quality drugs in a good prices for the population in Kuwait.

## 6.5 The Absence of a Quality Assurance and Service Management Departments in the Public Health Areas in State of Kuwait

The current deficiency of the Quality Assurance (QA) Department to examine the information on the quality of medications reaching the population was mentioned by a large majority of the interviewees (121, 82.6%) (Question 3 of the interviews, in Chapter 4). They indicated that this is a major weakness in Kuwait over its control of the quality of the Administration and Access for Patients to Medicines which have good quality, are safe and are efficacious for the use against diagnosed illness. The deficiency in checks on medicines was found across most public health areas (CMS Administration, Laboratories and Hospitals) in Kuwait.

The absence of QA and Service Management takes a number of forms 1).The assessments of quality (safety and efficacy) of medicines entering Kuwait and in the future the quality of medicines which may be manufactured in Kuwait. This is directly relevant to the developments within the NDP, 2).The second level of QA/Management is linked to the quality of medicines provided through procurement practices. 3) The quality of health service management and support to patients. These 3 aspects were commented upon during the study and limitation on the assessment of service at different levels was observed directly during this study at the Drug and Food Control Administration, CMS Administration, ten public hospitals and two health clinics (PhD study, 2012–2015). In addition it was mentioned during discussions with professional health care staff and through

observing the nature and operation of the work in these areas that the quality of service during the interaction with patients and the support given to patients should be examined (as mentioned in Chapter 5) and this could be introduced into the relevant section of the NDP.

From these observations on medicines quality it is recommended that the introduction of adherence to good QA (medicines and service quality) practices is featured in the NDP and that the KMOH should focus on the significance of QA and work together with health professionals to disseminate knowledge on this property in all public health areas, that work with and supply medicines and health support.

In particular it is the former aspect of QA which is given most attention in this study. By considering and operating good QA for medicines quality it will assist in developing and improving the health services in the country and support the work which will be carried out in establishing a NDP in Kuwait.

In this section, the following areas are discussed;

1. Definition of QA.
2. QA and the Drug and Food Control Administration in Kuwait.
3. Absence of a good management practices for drug procurement in the CMS Administration in Kuwait.
4. Absence of a quality of service assessments in public hospitals in Kuwait.
5. The importance of assessing excellence in developing the Health Care System in Kuwait.

### 6.5.1 Definition of Quality Assurance

QA refers to a process which ensures that medications which reach patients are safe, effective and can be used for that patient. The deficiency of a QA program, Departments or Organization has been observed during these studies and are thought to effect negatively on Kuwait's Health Services, and may be involved in

the risk of the government/MOH in procuring pharmaceutical products that could be sub-standard and may lead to product recall, wastage of money and most importantly health risks to individual/groups of patients that have been exposed to these medicines (WHO, 2007).

In addition to the reducing the effect on the patient, the presence of a structured QA program is very important in ensuring the control and monitoring of drugs, their drug testing and the analytical work carried out in the laboratories. It is important that testing laboratories through the QA Department are able to quickly exchange reliable data between laboratories and the drug enforcement agency, the CMS and where appropriate between laboratories on a national and regional or international level. Having well developed QA procedures in place which, work with analytical precision should have the effect of stimulating GLP (Good Laboratory Practices) across laboratories, which should have well trained staff and have a sufficiency of suitable instrumentation and access to methods. This should be under the control of the Food and Drug Control Administration to test for medicines entering Kuwait through the drug procurement program and where illegal drugs are suspected (United Nations, 1995). The Drug and Food Control Administration would also discuss medicines quality and QA testing where appropriate with the CMS. In order to undertake these suggestions it is important that within the NDP there is full discussion of a QA Plan which is operated in a way which is linked into the structure of the NDP.

### 6.5.2 QA and the Drug and Food Control Administration in Kuwait

From the knowledge base developed through studying the introduction of a NDP, knowledge from working in the Laboratories of the Drug and Food Control Administration for a number of years and the fieldwork visits to Kuwait (PhD study 2012–2015) (as discussed in Chapter 5), it is clear that the operation of the QA Department as a section of the Drug and Food Control Administration has a number of areas, where further developments are needed.

The areas which should be considered include; management and operational structures, the method of operation and the management control, training and update training of staff and its authority alongside other Departments. Therefore it is proposed that for a QA structure to operate affectively, it must have authority, to include the power to make and take decisions, to which other Departments and Areas should take heed. But presently in the Drug and Food Control Administration and other areas where the QA has involvement it is very difficult to achieve this without clear lines of authority and with very limited staff (presently they only have 2 pharmacist staff) to cover what should amount to a very large area of responsibility. As an example the management decision structure of medicines discharge after testing operates through the Registration and Release Supervision (Quality Control), rather than the authority and clearance through the QA Department, which is the internationally accepted chain of management.

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At the present time it is proposed that the QA Department are not working at the level which would be expected to ensure that the medicines entering Kuwait and stored in Kuwait in the CMS can always be said to be of the best quality, have been efficiently tested and that decisions have been taken which are sound on the basis of good quality assurance practices. Therefore the issues mentioned above are suggested to be causing obstructions in the work efficiency of the QA Department and consequently do not support the reaching of the desired goal; controlling and monitoring, accepting analytical and administrative work which should be carried out to allow quality testing and then 'signing off' and registration from the Laboratory Supervision. In addition to this assessment of quality and therefore the capability to indicate that the medicine reaches the required Pharmacopoeia requirements.

There is also the further stage of being able in the future to use a greater degree of assurance that when a medicines enters the circulation chain in Kuwait it has been tested efficiently and then if there are later problems with Post Marketing

Surveillance in Kuwait, (which would be introduced as a part of the NDP), any issues that arise can be reported as possible adverse drug reactions and not based on quality concerns.

Hence to develop and improve the QA Department in the Drug and Food Control Administration the first stage should be to ensure the structure allows enough management decision control and power to make decisions relating to quality (and where appropriate safety and efficacy) over other Supervisions and Departments of the Administration. In order to achieve this, the KMOH should make clear the role of the QA Department in written documents relating to the NDP and provide statements which promote the work of this Department. These could include; providing greater power of authorization to ensure that there is sufficient clear monitoring of the drug registration process and insisting that drug testing is carried out at the level appropriate in Kuwait and relate this to international testing, that there are the employment of a suitable number of staff and that all the staff are fully trained in procedures and processes appropriate for making decisions in QA. The QA Department should also collaborate with the CMS to ensure that medicines stored in the CMS and the medicines collected during inspections are tested. In addition, in particular the Department should be independent and divided from Registration and Release Supervision.

Communication is also of major concern and the present communication methods are suggested to be inadequate to handle the needs of the Administration. As a result electronic methods of communication are considered to be essential to ensure that the QA Department can provide the high level of support needed. Accordingly an e-link system between the Supervisions and Departments of Drug and Food Control Administration and CMS Administration to ensure provision of more efficient communication and faster response to decision making to ensure that medicines procured for Kuwait and used in its Health Areas are of the best quality, safe and efficacious.

### 6.5.3 Absence of a good management practices for drug procurement in the CMS Administration in Kuwait

Based on the structured discussions with pharmacists (in CMS Administration) (presented in Chapter 4), and information provided on the drug procurement system (mentioned in Chapter 5) and informal visits to the CMS Administration during the PhD study (2012–2015), it can be indicated that this Administration suffers from management limitations in areas relating to ensuring the best practices are operated in the procurement of medicines through the CMS. A lack of quality of practices in this Administration was considered by interviewees to be acting negatively on monitoring and evaluation on the work of CMS Administration relating to procurement of medicines and the Procurement Cycle which is operates in Kuwait and many other countries.

It is proposed that the CMS should establish a section of the department which would support the Drug Procurement Process and ensure in an independent format to assess the management procedures of:

1. Identifying the prequalification of drugs and medical devices before procurement.
2. Examine the processes of purchasing of drugs.
3. Ensure good storage and record keeping of purchased drugs.
4. Introduce effective control of drug distribution.
5. There should also be links with the QA Department in the Drug and Food Control Administration for medicines testing

#### 6.5.3.1 Identify the prequalification of drugs and medical devices before procurement

According to the information obtained during field visits to the CMS, it is suggested that the KMOH can improve the process to identify the prequalification of drugs and medical devices before procurement by establishing an improved

management department in the CMS Administration. The procurement practice which is recommended, is a continuous cycle from year to year and has been discussed in the textbook, Management Science and Health Publications – Managing Drug Supply in collaboration with the WHO action programme on essential drugs and this text should be examined and compared with the procurement practices in Kuwait to ensure the best practices for medicines procurement in the public sector (MSH, 1997).

Added to the information source above a WHO team of specialists in 2003 found that there was a substantial difference between the prequalification of vaccines and pharmaceutical products (WHO, 2003).

Prequalification of drugs is a term given to a service or a system which examines the choice of medicines through assessing their quality, safety and efficacy. The first major form of prequalification was carried out as a directive from the World Health Assembly (1997) to the WHO to request they set out the basis for an Essential Medicine Programme of prequalification and every 2 years the list of medicines is examined closely and some are added and some are removed based upon their quality, cost and health value and by the end of 2012 the list contained more than 316 drugs (WHO, 2013).

The process of prequalification as proposed by the WHO consists of five steps, which includes:

1. Firstly an invitation is made to product manufacturers to submit products for evaluation. (Only approved drugs on the Essential Drugs List, are evaluated). The Drugs on the List having been selected on the basis of public health need, effectiveness in comparison to other products, their safety and cost. But as Kuwait does not have an Essential Drug List to work

with under their CMS drug procurement system, it is important that the KMOH work with the CMS on establishing this list.

2. It is proposed that the manufacturers are responsible for providing their own data on the quality, safety and efficacy of their product which includes data on the ingredients, to include the purity, and also where appropriate to provide data from clinical trials in healthy volunteers.
3. This data should then be gathered together and analyzed by the health professional from the procurement management.
4. It is normally the case that the MOH sends a team of inspectors to the manufacturing site where they can ensure that the site complies with GMP, and this extends onto any contractors, such as other laboratories or companies carrying out manufacturing of the pharmaceutical preparation or clinical trials, who both have to comply with either good clinical or laboratory practice.
5. A decision is then made based on whether the product meets the requirements of prequalification, and the drug in the required pharmaceutical form is then added to the list of prequalified drugs. However at present this set of procedures can take from three months to considerably longer if the manufacturer does not meet the required standards. The MOH continues through the CMS medicines inspection team to visit and ensure that the product continues to meet specifications and also to account for any variations made to the product (WHO, 2013).

In the information gathered during the study there were concerns that the different processes of drug procurement could be tightened and improved with a dedicated management team and In particular, not having and Essential Medicines List can be said to reduce the effectiveness of the present medicines procurement system and can lead to difficulties in maintaining medicines supply and in obtaining the best prices for the medicines required. With a dedicated Management Team in place to oversee the procurement practices and to follow the other stages of medicines storage and management, there is likely to be a closer liaison with the QA in the Drug and Food Control Administration leading to the exchange of data

among the Supervisions which is considered very important to ensure medicines procurement of the best quality and provide the best financial position within the budget provided.

6.5.3.2 Purchasing of Medicines.

One of the major functions of a Procurement Management Teams in the CMS is to obtain medicines at the best possible cost, within the government budget and therefore the processes used in the purchasing of drugs by the CMS Administration in Kuwait, is highly important.

The overall aim of purchasing is to obtain good quality, effective and safe drugs at the lowest cost possible. There are four main goals which ensure good purchasing of drugs (Managing Drug Supply, 1997) and this applies to any system which can be both public and private. These are the 1) ensuring the value of the drugs in an Essential Drugs List and selection of reliable manufacturers or suppliers, 2) purchasing of the most cost efficient medicines in the right amounts, 3) finding the time it will take for delivery and 4) ensuring the medicines total costs to include all aspects of the purchasing cost (e.g. packaging, shipping, storage on receipt before QA clearance (WHO, 1999). The QA Department in the Drug and Food Control Administration can support the health professionals of the Procurement Management Team in the CMS in these actions by provide a data base of quality concerns and stability information to assist in finding the best drugs/medicines for use in the public health system. They can also through the Laboratories provide medicines quality data (QA data) both initially and during medicines storage.

It is proposed that there can be four main methods for purchasing of medicines after the processes above are handled of; selection of products and manufacturer, list of quantity and specifications. These include;

a) ***Restricted tender***, any manufacturers considered are already preapproved through prequalification. This can be referred to as limited international bidding. This method ensures quality products are selected from reliable sources.

b) ***Competitive negotiation***, quotations for price are obtained from suppliers, and the lowest price is usually selected. This method is useful when obtaining a small quantity of medicines.

c) ***Direct procurement***, pharmaceutical products are purchased directly from a supplier without any applications or price comparisons. This may be used when there is only one supplier for a product.

d) ***Open tender***, all manufacturers are allowed to bid and this can be referred to as international competitive bidding. This can be a long process and is generally inadvisable as it can be uncertain whether the supplier will be able to deliver the specifications (Managing Drug Supply 1997).

6.5.3.3 Storage of purchased drugs

As mentioned in Chapter 5, medicines storage of purchased drugs is carried out at the warehouse of the CMS Administration and the company which acquired storage tender will be responsible for arranging the drugs storage in the warehouse of the CMS. Presently the overseeing of this storage is loosely carried out within the CMS, but the introduction of a Procurement Management Team should have greater control of this storage function and ensure enough control and monitoring over the Companies operations by ensuring that all the stored drugs are under conditions set out by the KMOH and from this prepare electronic reports on the level and quality of their work.

The Procurement Management Team will be important in ensuring that the receipt of medicines into storage is constantly updated by the CMS staff and the storage conditions are maintained in order to ensure that their quality is preserved. The

CMS staff should ensure that the batches can be traced and the stock can be rotated and this would be overseen by the Management Team. Another function would be to liaise with the Drug and Food Control Administration Analytical Laboratories to ensure that samples in each batch of product are be chosen by the Drug and Food Control Administration QA management and tested within the Drug and Food Control Administration laboratories to ensure that meet the specifications, prior to supply of the product. When receiving a delivery of product, not only should their transfer be protected, but it should also be traceable and the product should be quarantined until it is cleared for use. The Procurement Management Team should ensure that any products deemed to be rejected should be marked and stored separately so that they cannot be used and their disposal arranged. The storage conditions should also be appropriate, and comply with manufacturer's instructions, which protect the integrity and quality of the product (WHO, 2003) (It should be noted that stated temperatures for example may in-fact mean a range as demonstrated in Table 6.5).

The overall conclusion of these studies shows the importance of establishment a Procurement Management Team in the CMS Administration to ensure enough control over the Procurement and Medicines Storage in the CMS store and it is suggested that the management structure should appear in the NDP and the KMOH should carry out this necessary action in the future plan.

**Table 6.5 Manufacturer instructions and equivalent conditions (adapted from WHO, 2007)**

| Label | Conditions |
|---|---|
| Do not store over 30$^{o}$C | Between +2$^{o}$C and +30$^{o}$C |
| Do not store over 25$^{o}$C | Between +2$^{o}$C and +25$^{o}$C |
| Do not store over 15$^{o}$C | Between +2$^{o}$C and +15$^{o}$C |
| Do not store over 8$^{o}$C | Between +2$^{o}$C and +8$^{o}$C |
| Do not store below 8$^{o}$C | Between +8$^{o}$C and +25$^{o}$C |
| Protect from moisture | Conditions must be below 60% humidity |
| Protect from light | Must be kept away from light |

6.5.3.4 Effective control of drug distribution

Based on the information presented in Chapter 5, it is indicated that The CMS Administration is responsible for distributing medicines to the public hospitals and clinics. The final step within the Management Teams remit of product procurement is the effective control of distribution.

Appropriate distribution systems should be in place to maintain a supply of drugs, of good quality and condition at all stages of the process, good inventory records should be kept, theft should be reduced and adequate forecasting by systems for future demand established (MHRA, 2011).

It is clear that the establishment of a Procurement Management Team in the CMS Administration in Kuwait should improve the supply management of drug selection, procurement, storage and distribution within this Administration.

As has been indicated the reassessing the processes of Medicines Procurement should be continuously monitored. These include the suppliers and manufacturers who should continue to be re-evaluated, and it is suggested it should be at least every three years and any changes made by the manufacturer should be noted as this may have an effect on prequalification. Secondly the Quality Assurance System undertaken at Drug and Food Control Administration should aim to re-evaluate products after a period of time; this is especially true if the product needs to be retested as a result of a change made to the product characteristics.

Thirdly, the contractor should also be monitored, particularly with regards to storage and distribution of products, where all transport and storage should be traceable. As indicated above, one of the most important areas for QA monitoring is carried out by the Drug and Food Control Administration Laboratories where the methods of testing, and the analytical results should be subject to quantitative and qualitative assessment to ensure the methods and the statistical results are appropriate to assess the quality of the medicines. While carrying out this quality testing the quality of medicines from outside the country, there should also be statistical measurements of the analytical performance of the Laboratories in each of its areas of assessment. The assessment of results from the laboratories is a continuous process to ensure that the performance does not waiver with time. Finally research organizations attached to the Laboratories should also be quality assessed to ensure they continue to deliver quality in development results and for clinical standards (WHO, 2007).

### 6.5.4 Limitations of not having a Performance Assessment Team in public hospitals in Kuwait.

The structured discussions with professional health care staff (Chapter 4) during the PhD study (2012–2015), and information gained during informal visits to 10 public hospitals, it was indicated that there is an absence of a Performance Assessment Team who work with the Administration and with the Health Professionals.

Such a Team would be expected to carry out performance checks at a number of levels within the hospitals and could be made up of Health Administrators and Human Resource members. The main function of such a team would be to monitor the overall performance of the different health service personnel, without specifically looking at individual performance, the facilities and the overall experience of the patients to their time as in- and outpatients In addition to the assessment of the service provided of the Pharmaceutical Administration in delivering the sport service. Individual performance review would also be assessed (physicians, pharmacists, dentists, nurses, auxiliary staff and technicians) but this would normally carry out in conjunction with the Human Resource Department in an individual or group of hospitals and handled as a performance review. The area of contact with patients and the service provided for these assessments would be varied in many cases, with the range spanning; pharmacies, medical wards and clinics, biochemistry laboratories, dental clinics and operating rooms.

The benefits of establishment of a Performance Monitoring Team in public hospitals in Kuwait, includes:

1. Ensuring that all prescribing and dispensing drugs in the public hospitals are of high quality, safety and efficacy and cost effective for treatments and the patient is satisfied with the service received.
2. Ensure that the patients and other health professionals are satisfied with the level of health support given in the public hospitals, which has the advantage that developments from these assessments are likely to increase the efficiency of the support to patients.
3. Ensuring that safe guards are in place to reduce medical errors.
4. Ensure that the work procedure overall of health professionals meet the needs of the Health Care System.
5. Increases the ability to identify medical, health, management and patient service problems and being able to find solutions for these problems and

preparing improvement plans for development of health services in the future.

6.5.5 The importance of improved quality of service in the development of the Health Care System in Kuwait

The overall conclusion from these studies across a wide range of pharmaceutical/ medical service delivery is firstly the need of an Essential Medicines List for Kuwait. In terms of the medicines dispensed there is the requirement for greater assessment of incoming medicines from outside the country and the quality of health service provision to the patient in the pharmacies, clinics and hospitals. These aspects are only likely to improve, if there is a degree of Management involvement of; the quality of medicines through a QA Department with powers of decision in the Drug and Food Control Administration, in the procurement of medicines through a Procurement Management Team in the CMS, and in the service provision by greater assessment of employee and facilities performance of Health and Support Staff at all levels, which would normally be handled through performance review carried out by the Human Resources Department and the Service Provision to patients through Facilities Management. Each of these management functions should be strengthened as part of the development of the NDP. The main points from the proposal are that there should be improved control, monitoring and evaluation of work, medicines and facilities in the following areas:

a. Drug registration and testing in Drug and Food Control Administration.

b. Drug selection, procurement, storage and distribution in CMS Administration.

c. Drug prescribing, dispensing, medical and pharmaceutical services in the Public Hospitals.

## 6.6 The Deficiency of an Essential Medicines List in Kuwait

95% of interviewees (in Chapter 4) supported the importance of the introduction of an Essential Medicines List for Kuwait. It was suggested that the selection of an essential or restricted drugs list for Kuwait is probably one of the most important issues of developing a national drug policy and it could be described as one of the principal reasons behind the efforts to design, implement and regulate a NDP.

To ensure the success in establishing an Essential Medicines List (EML) in Kuwait and gaining the expected advantages and benefits from its introduction it is suggested that the KMOH should firstly study and understand the concept of an Essential Medicines List and identify main core elements of this policy development. Secondly the KMOH should analyse the process of selecting drugs in the CMS Administration (as described above for medicines procurement) and to determine if the current processes go any way to meet the appropriate needs of the population. Thirdly to take advice from other developing countries who have succeeded in introducing an EML to include; Namibia, Kenya and Oman (as mentioned in Chapter 3) and view the WHO Model List and recommendations, as a starting point for developing a List for Kuwait. Developing such a List will require the gathering of a large amount of medicines information both on the drugs themselves and on the best basis for the needs of Kuwait. Once the collected data from public hospitals, health clinics, health centres, pharmacovigilance centres, country wide medicines regulators, e.g. Food and Drug Control (FDA) in the USA, European Medicines Agency (EMA) in the EU and many other Medicines Regulators and the WHO and the private sector is gathered and analysed and information discussed by a Committee of Health Professionals, Scientists and Administrators the medical value, disease state needs, cost effectiveness and clinical treatment guidelines, should be consulted, there should be a list of medicines found which are suitable for the needs of the population in Kuwait (and represent the most used and needed drugs in the State), and these Drugs/Medicines can become Kuwait's EML.

In this section, the following aspects are discussed:

- Definition and main importance of EML.
- WHO Criteria's of selection essential drugs.
- Process of drug selection in CMS in Kuwait
- Advantages from having an EML in Kuwait.

### 6.6.1 Definition and importance of EML.

Drugs that fulfil the health needs and concerns of the people are described by the world health community as Essential Medicines. In 1977 the WHO introduced the first Model List of Essential Drugs which is reviewed every 2 years by the WHO Expert Committee on the Selection and Use of Essential Medicines (WHO, 2007). According to the definition proposed by the WHO, Essential Medicines are considered to be "those that satisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts, in appropriate dosage forms and at a price the individual and the community can afford" (WHO, 2001).

The number of different drugs produced worldwide from many different processes is very large and there is no countries health organization which can provide all the drugs available in the global environment and it is the case that only a limited list of these drugs are really necessary to provide health support to populations. Therefore there is an advantage in implementing a form of an EML which is based upon the clinical value for treating health conditions, along with guidelines specifying the active use of the drugs in therapy (Tetteh, 2009).

The WHO 1977 list originally included approximately 200 drugs and vaccines by generic name (Reich, 1987). The most significant challenges that EML Selection is

faced with is acceptance of the limited number of drugs by the health fraternity, consumers, pharmacies and manufacturers. Also there has been in the past objections to the introduction and enforcement of the EML in the private sector and the control of non-essential drug donations which are required to support drug shortages. (WHO, 2001)

Each nation may have their own list of drugs in the EML and the WHO EML may only act as a guide for choice of a nation's individual essential drugs. This is understandable as the priorities in terms of disease treatment will be different in most countries, however for poorer developing countries there is generally some commonality between countries choice and the WHO List. It was the case at the beginning of discussions at the World Health Assembly and with the WHO that the main purpose of an EML was to; make available appropriate medicines for the countries health needs at all times, in the appropriate quantity and dose, with the assurance of its quality, to provide suitable health information for the individuals and the community, at the most affordable cost.

Examination of the Medicines Market reveals that there are a considerable number of drugs available, many of which can be described as being excessively charged. But a country EML should provide cost effectiveness value, but still maintain the major aspects of quality, safety and efficacy. An EML is generally based on clinical and health needs, clinical value, together with the medicines cost effectiveness, (Sekhar Kar et al., 2009)

There are also other advantages and uses for a well organised National EML. The most apparent is it will be the basis for the management's public sector medicines procurement and distribution policy. However there are also advantages of having a limited list in health education and training of health professionals and a major advantage of having a structured list when informing the general public about their use. In addition, from a financial viewpoint for those who have health insurance, an EML is often consulted by insurance companies in order to formulate their insurance policies as far as coverage of drug reimbursement is concerned (WHO, 2001).

### 6.6.2 NDP and selection of Essential Drugs

National Drug Policies seek to establish regulatory frameworks to ensure the sustainable development of the pharmaceutical sector and the provision of pharmaceutical medicines to citizens in a country (WHO, 2003). Regardless of where in the world we are, this is a considerable task, with legal, medical, logistical and financial hurdles to overcome. Ultimately, a NDP aims to ensure people have safe access to high quality drugs when required, and it is safe to say that successful NDPs are tailored to the needs, resources and capacities of the country in question, and one size does not fit all.

The first piece of convincing evidence that NDPs can alter the healthcare and pharmaceutical landscape concerns the fact that more and more countries have NDPs as time goes on. In short, this means that more people globally appreciate the need for medicines to improve the quality of life. At present, more than 70 countries have implemented their own NDP, although vast portions of Africa and Asia still live with very poor access to essential medicines or medical professionals. Compared to 1977, when 2,100,000,000 people had access to medicines, 3,800,000,000 were served by 1999 (WHO, 2003), and more are predicted to be reached today. In general, the past 50 years has seen big strides made in the provision of safe and affordable medicines to more impoverished areas of the world, although much more remains to be done. In future, established NDPs will make it easier to procure and distribute drugs and increase the quality of life.

During the past few decades, National Drug Policies have helped increase public access to drugs in a major way, and given that the WHO reports that essential medicines are underused globally, their number needs to increase further. It remains unacceptable that millions of people are at risk of dying from highly treatable bacterial infections due to a lack of medication (WHO, 2013).

However, before considering the diverse issues influencing the establishment of a NDP, it is worth remembering the bureaucratic and financial implications such a move would have on a government. For example, in a developing nation with poor internal infrastructure, a NDP would struggle to find distribution solutions, and may not be their top priority. The successful implementation of a NDP, therefore, requires a concerted effort across different branches of government, and will require continual evaluation and editing to keep it in-line with best practice as new medicines are developed. Those responsible for the development of the NDP will need to employ a team focused on communications with the pharmaceutical/biotech industries so that solutions to supply and demand problems, for example, can be dealt with efficiently and in the best way possible. By working together, governments and pharmaceutical corporations have great power to shape our healthcare environment, and given their shared interests, it is safe to say that one influences the other, and vice-verse. Indeed, governmental matters affecting pharmaceutical business is not restricted to NDP development and implementation, but also compound registration and licencing (Carrese and Rhodes, 2000).

Indeed, should funds be available to pursue the endeavour, a primary limitation to the implementation of a NDP is selecting a drugs list. There are many thousands of clinically-established medicines globally, and many different drugs are used to treat the same condition. When setting up a new NDP, drugs will need to be selected according to budget, population needs and availability. Accordingly, the generation of the NDP drug list alone will require extensive epidemiological and statistical analysis from basic researchers with experience of their country's healthcare needs. The drugs list should also be regularly updated and benefit from the latest medical research knowledge and expertise to deliver maximum benefit to patients. In the UK and other nations, government-independent bodies are charged with overseeing medicines (and technology) selection and purchasing for the NHS, and have received repeated public criticism for drug selection policies, demonstrating the scale of the task at the population level (Chaplin, 2014).

However, selecting drugs can be viewed as the easy step. Agreeing a price with the pharmaceutical companies can be a drawn-out, difficult process, with private companies seeking to protect their ability to invest in future products (Landers, 2017). That said, it has been reported that large-scale agreements between countries, such as the UK and UAE, and pharmaceutical companies have been reached to ensure a fair-pricing structure is in place to generate a sustainable industry going forward (Khoja and Bawazir, 2005; Morgan et al., 2008); after all, we need new drugs and companies need to sell them. Importantly, aging populations worldwide (driven by our increasing access to modern clinical medicine) will lead to increased drug requirements in the long-term, necessitating countries to plan for the occurrence in advance so that they are able to develop sustainable financial policies.

Despite collective buying power, and pricing frameworks, many drugs under patent are prohibitively expensive even for the wealthiest national healthcare systems and are only available to wealthy individuals with private medical coverage (Ghinea et al., 2016). For example, some new anti-cancer monoclonal antibody treatments cost hundreds of thousands of dollars per year of treatment, with top selling medicines raking in billions in annual sales (Siddiqui and Rajkumar, 2012). Accordingly, poorer countries with smaller health budgets are unable to acquire the medicines they need in sufficient quantities. Again, countries working more closely with the pharmaceutical sector seem to be the way to go to improve relations and agree pricing structures that benefit both parties. Although recent years have seen large biotech companies increasing their participation in charity endeavours – including donating/selling at reduced price essential medicines to the developing world – these examples are the exception rather than the norm (Gottlieb, 2000), and western pharmaceutical companies should increasingly look to be more flexible in the global marketplace to increase the quality of life worldwide.

As touched upon previously, a successful NDP requires the means for drugs to be purchased, distributed and securely stored, something which is more easily achieved in different parts of the world (Strang et al., 2012). Medicines requiring a cold-chain, for example, are difficult to provide to very remote populations with intermittent access to electricity. Therefore, infrastructure is vitally important, and could represent a considerable investment if greater numbers of people are to be reached by a NDP.

Aside from the challenges faced before we reach the bedside, the introduction of a new NDP will also require additional training on legal and medical topics for doctors and nurses in the healthcare system concerned (Leung et al., 2013). A new NDP may bring with it several new medicines that were previously unavailable, and new types of paperwork to control drug use, all of which will bring their own learning curves. The application of new medicines will also require additional follow-up studies depending on the population, as different drugs can have very different effects in different ethnic groups (Xie and Frueh, 2005).

Further down the line, and during the implementation phase, litigation and legislation are likely to feature prominently and will consume much effort, not only in the establishment of new deals with private corporations, but also from civil right groups wanting to ensure appropriate checks and balances are in place in the policy to protect the public (Harpwood, 2016). Government work and law making cannot be understated as time-consuming requirements for the implementation of any NDP. New NDP frameworks will also need to control for corruption and advertising which influences a doctor’s decision to administer any particular treatment.

### 6.6.3 WHO Criteria for selection of Essential Drugs

A criteria has been suggested which can give guidance to MOH Departments for selection of drugs which could be included in an EML. Initially it is proposed that a committee of knowledgeable experts in their fields of pharmacy, pharmacology, and clinical medicines can be set out and the information taken by this committee can be in the form of consultations with pharmaceutical companies, professional associations and organisations linked to patient groups. For the drugs to be considered they should have positive proof of their clinical efficiency and benefit. These drugs should have been shown to be safe under adverse drug reaction monitoring in the short and long term and in the presence of different types of health disease. Another major consideration would be the cost effectiveness, where medicines can be compared not just on the unit cost of the medicine but when comparing two medicines the total cost of treatment can be given importance over unit costs but also the total cost of the full treatment alongside the efficacy of the drug(s) could be considered. Additional factors which can be studied are pharmacokinetic properties or any special storage or manufacturing facilities. Drug should be available in an adequate form to confirm its quality, bioavailability and stability. Generally a medicine should be a single compound or in a fixed ratio of compounds where it can be shown there is advantage over a single drug medicine when taking into consideration drug safety, patient adherence and their clinical effect. (Sekhar Kar et al., 2009)

It is suggested that the need for specific diagnostic facilities and treatment requirements can also be a factor in some in medicines choice for a List. Comparison should normally be made within a therapeutic group and not among a therapeutic category (For example, the treatment of HIV and the treatment of malaria). On occasions there may be an absence of scientific evidence for priority disease treatment, and in this event the expert committee may decide to postpone selection until further information becomes available. (WHO, 2002)

In addition to the general EML, specialist areas of health problems have regularly been considered over recent years by the medicines regulators, such as the Drug and Food Control Administration in the USA and the EMA in the EU and the WHO

in recent years. Typically work programmes on areas such as paediatric medicines, for the elderly and orphan medicines which have found their way into EML.

The case for introduction of an Essential Medicines List in Kuwait is convincing, particularly when the number of different medicines brought into Kuwait each year and the very high cost of procuring these medicines is taken into consideration. The criteria that are recommended can be used to establish an EML is persuasive. The KMOH can use the reasonable large information base and take information from other similarly sized developing countries experiences in setting up an EML. In doing this the KMOH should also take into consideration the individual differences between countries on disease prevalence, demographic and financial conditions, healthcare service quality and availability of appropriate healthcare facilities. These differences the health professionals in Kuwait can determine and set out a programme to find the best mix of medicines in the EML for Kuwait, according to their experience.

### 6.6.4 Process of drug selection in CMS in Kuwait

It is clear that (as mentioned in Chapter 5) the CMS Administration is responsible to purchasing drugs for the public sector in Kuwait. The current process of drug selection for purchasing in the CMS Administration however suffers from a lack of an EML and is only based on the decisions of the committees between the CMS and the Council Medical Departments (consisting of physicians from several medical specialities), where physicians suggested the appropriate needs of drugs for the population based on their experience and sometimes from outside advertising and seminars.

Based on the structured discussions with health professionals of the CMS (Chapter 4) and the collected data from the KMOH (Chapter 5), it can be observed that the

process of drug selection suffers from many issues (See below) and may not effective because it is not based on clinical studies and treatment guidelines, which related to a number of prescribed and dispensed drugs in all the public hospitals and health clinics. In addition the Council Medical Departments have regularly not enough information about medicines (clinical study, stability study, bioequivalence studies and cost effectiveness) and they have not recent information about updated drugs. According to the information presented the researcher was alerted to the existence of some problems that don't help in the development of drugs selection and purchasing and the results found ensure the importance of establishing an Essential Drug List in Kuwait. From the PhD studies it was found that:

1. There was a large wastage of medicines and it was found that the total amount of the expired drugs in the CMS from 01/01/2013 to 31/12/2013 was estimated to have reached 5,75 million $ (See Chapter 5).
2. Physicians and consultants in the public hospitals ordered products and after short time they changed their order and asking for different drugs.
3. Many of purchased drugs are not meet needs of population or purchased from non-qualified manufacturers especially from GCC countries.

Therefore it can be suggested that it may be necessary to carry out establishment of an EML in Kuwait to solve the issues mentioned above, in addition the KMOH should also considered that, clinical guidelines and the EML should be reviewed regularly (a likely interval would be every 2 years) in order to ensure adherence to the policy standards and assess the impact of these compounds on the population (WHO, 2001).

### 6.6.5 Advantages from having an Essential Medicines List in Kuwait

The EML is therefore a very important factor for the development of the Health Care System. It is possible that the State of Kuwait could begin to start thinking

about establishing a list at an early time to overcome the issues resulting from lack of an EML and to satisfy the health care needs of the majority of the population.

The establishment of an EML in the State of Kuwait can be developed and improve the Health Care System through:

1. Savings for the national budget.
2. Reducing the expired drugs in CMS warehouse.
3. Ensuring the availability of the appropriate needs of drugs in a long term.
4. Supporting to have a vision for a long term program for the specific needs of Kuwait.
5. Ensuring the availability of drugs for sustainability of the health system.
6. Purchasing of most cost efficient medicines in the right amount.

### 6.7 Insufficient training programmes for health professionals in Kuwait

The majority of the interviewees (64.5%) suggested that the training/update training programmes for health professionals were not sufficient, especially for the senior pharmacists, as there are a lack of an effective training programmes to support them in understanding how to develop and improve their pharmaceutical knowledge.

They also suggested that the lack of training programmes in new areas of pharmaceutical services limits pharmacists' knowledge and means they cannot update their pharmaceutical information for patients. Most interviewers suggested that increasing the amount of participation in international scientific conferences (and providing funding for attendance) is one a way to develop new knowledge in the profession.

It is clear that human resources form the backbone of a Health Care System and therefore a sufficiency of staff is an essential component. In Kuwait the Government and MOH cannot function efficiently, manage, oversee and finance programmes if the workforce is insufficient to be able to carry out the tasks, which can often be specialized (Rockefeller Foundation, 2003).

In that respect even with a full workforce, training programmes are a very important aspect and directly affect the work of health professionals and they can determine the degree of success of the work of the Health Care System.

Thus the importance of human resource development and training programmes for health professionals cannot be overstated. It is important that the MOH introduces the appropriate type of training programmes for the pharmaceutical sector in Kuwait, and within these needs there is the requirement of training programmes that support the implementation of a NDP in Kuwait.

### 6.7.1 Human resource development

Human resource development has often been thought of as organizing courses for workforce training, and whilst this is a part of human resource development, it should incorporate a wider field to include vocational education, training and management of professional development. Often education has been seen as separate from training because it involves undertaking academic learning in the pursuit of a qualification, which would then lead to employment (Gibb, 2011). Here the role and duty of the Kuwait University (School of Medical, Pharmacy, Dentistry and Nursing) is to provide appropriate educational courses for students, endeavour to use suitable and the latest educational curricula and contract with a qualified educational team. It is also suggested that the KMOH could cooperate more with Kuwait University and contribute to improving health education by allowing an increase in the number of student visits to public health areas (hospitals, health clinics, labs and administrations), which would help the health students to

recognize and practice the nature of the work before graduation. Training, on the other hand, comprises learning to develop skills for work whilst in or out of work, which would enable good performance within the work place setting. Development is seen as separate from education and training, but is also associated with both. Development can occur during the person's growth through their education and training and then in their job, and normally involves on-the-job experience (Gibb, 2011).

Development can also be about a change of the whole person, and so it is an integral part of the working life of an employee. Human resource development is a process that includes dealing with the process of facilitating, guiding and even coordinating learning of individuals so that the individual, team or even organization can perform in the way that is desired by the system. It is important to note that human resource development as a whole should identify the needs of the individual. This is because a new junior doctor may have different developmental needs to an experienced consultant, and this presents distinct challenges. It can be summarized that work-related development is a combination of three elements. 1) Cognitive capacity, which is the ability to process learnt and memorized information. 2) Cognitive capability, comprising the many abilities involved in the employment; these may be innate or learnt. Finally, 3) Desired behaviour of the individual, can be summarized as the attitudes, values and emotional intelligence of the individual (Gibb, 2011).

Cognitive capacity can be divided into two views, modular and unidimensional.

The modular view takes into account degrees of complexity, specifically with regards to memory skills, language skills, analysis, reasoning, and hypothesis testing like thinking, decision making, problem solving and creative thinking (Halpern, 2002). On the other hand, a unidimensional view of cognitive capacity includes the ability to remember and understand, apply and analyse, create and evaluate (Anderson and Krathwohl, 2001).

There are a number of ways in which the human resources department within the University/KMOH can facilitate development; this may be via on job training, mentoring, formal education, training facilities, conferences, internet- and intranet-based and non-electronic open learning (Gibbs, 2011).

According to the information presented above it can be suggested that it may be necessary for the KMOH to carry out support development in the types and views of the human resource development (mentioned above) to ensure that the training/support programs for health professionals are based upon solid foundations.

### 6.7.2 Training programmes for health professionals in Kuwait

As mentioned at the beginning of this section, the majority of the interviewees indicated that there was insufficiency and defects in the KMOH training system, and specifically there was no training programme for pharmacists to develop their work or to update their clinical and scientific knowledge (except one programme for pharmacists who were recent graduates). This is whether they are working in hospitals, health clinics, health centres or pharmaceutical administrations.

In some pharmaceutical administrations, there is also a lack of training programmes in some aspects of the process that can be considered to be at the core of the work (e.g. a lack of GMP and inspection training programmes for health staff in the Drug Inspection Administration).

Therefore as a conclusion to the discussions at the interviews with health professionals (especially pharmacists) and through several visits to the various health care environments to observe the nature of the work of these areas, it is suggested that KMOH should provide a number of training programmes for the

health care team to develop their work and ensure quality performance of the working staff. Based on the results obtained, it is recommended that the KMOH organize training systems for health professionals according to the needs of both the health care workplace and its staff.

From the research studies it is possible to suggest that the KMOH organize training programmes for each health area (public pharmaceutical administrations, hospitals and health clinics) to include:

1. Giving a greater role to the Human Resource Development Department and giving them more power and authority to play a primary role in supervising the training of health professionals by providing the necessary training courses, and supporting health professionals in attending local and global conferences. Also giving them responsibility for following-up training programmes and up-skilling of the scientific aspect of courses and to increase the knowledge of health staff cadres able to give training to the rest of the staff.

2. Development of a specific plan of action in cooperation with Kuwait University to help the KMOH to provide the necessary training courses. From observation and discussion with the Vice Dean of the Kuwaiti Faculty of Pharmacy and the Head of the QA Department, during the Research Interviews for this study, in 2013, it was suggested that the Faculty of Pharmacy could provide specific courses for training KMOH pharmacists (e.g.; in QA, Quality Control, Drug Inspection, GMP, GLP and Supply Management) and these courses were unlikely to be charged for, by the University, but would be provided in order to support the KMOH's development and to improve Kuwait's health services.

3. Providing training programmes for pharmacists who work in public pharmacies, including programmes in:

a) Communication skills with patients.
b) Communication skills with other health professionals, within a health care system, where groups of health professionals work together in teams. These could include doctors, nurses, pharmacists and other health related groups. It would be expected that there would be a coordination of their activities and discussion of cooperation to make patient care a priority. Overall, it is suggested that teams are susceptible to less error than individuals working on their own; this is because a team member may not only know their role, but also the responsibilities of other individuals (Sims *et al.*, 2004); this is likely to be the case if the KMOH provides a training programme system to ensure that everyone in the team gets adequate training.
c) Pharmacy practice.
d) Clinical pharmacy, to ensure that the pharmacists renew and update their information and knowledge.
e) Medical errors, to reduce the errors in prescriptions and maintain patient safety.

4. Improving the work of Drug Inspection Administration by provide training programmes in:

a) GMP (Good Manufacturing Practice) Courses. It was reported from the study that most medicines inspectors who are responsible for inspecting the local and international drug industries through the GCC inspection committee had not attended GMP courses and did not have a GMP licence.
b) Drug Inspection Course. New medicines inspectors depend on the experience of their colleagues to learn from and understand the ways and methods of inspection in Kuwait, The main reason for this is because there is a shortage of guidelines and a lack of training courses for drug inspection.
c) Drug Counterfeiting Course, to learn more about the problems of having counterfeit medicines enter Kuwait and to discuss ways of reducing the entrance and production of these medicines into the country.

5. Organizing a number of training programmes for the health care staff of the Drug and Food Control Administration, where there is a lack of training programmes in:

a) GMP studies.
b) GLP studies.
c) Clinical studies.
d) Stability studies.
e) Bioequivalence studies.

All of these studies are important and necessary for the health staff who works in Drug Registration Departments and Laboratories, and it is suggested that they should undertake these studies to ensure that all the registered drugs are safe, of good quality and efficacious.

6. Provision of annual educational courses on pharmaceutical legislations and regulations that are applicable in the KMOH, to ensure that all pharmacists understand the rules and know their rights and duties.

7. To develop and improve the work of CMS by providing a training programme for the health care staff working in:

a) Drug Procurement.

b) Supply Management.

c) GMP.

It is accepted that training for health professionals has an impact on the attitudes, knowledge and skills of trainees, which in turn serves to develop their skills, which translates directly to the care given to patients and is reflected in improving health care services (Boonyasai *et al.,* 2007). Nevertheless, researchers conclude that training should be a part of a curriculum for health care students, as well as being

available to professionals to ensure efficacious professional development (Ongrinc *et al.*, 2003).

Overall, it can be summarized that a successful human resource development, which includes training opportunities for health care professionals, is critical in providing quality critical care. Effective training strategies and perhaps more research are required to enable development that is most successful and shows highest efficacy (Kabene *et al.,* 2006).

Human resource development can lead to development of the Health Care System if the innate human resources are also developed, resulting in increased productivity, eradication of errors and overall change in the working and social life of health care professionals as they would be able to progress within their careers, allowing others to take over their old roles and continue to develop themselves. This would allow a system that maintains a highly trained workforce (Tailal, 2008).

Finally, the organization of the training process and increase in the provision of training courses is likely to develop and improve the professional work of health staff. This should then be reflected positively in the work in health care services through an increase the level of competence of health professionals and especially the senior staff, a reduction in the need for more staff for health areas, a reduction in medical and administrative errors. Having quality training guidelines will enable the training of health professionals and can be develop their efficiency in the future, where it will support the implementation of a NDP in Kuwait.

## 6.8 Weakness in control over the medical outcomes and adverse effects of medicines administration in both public and private sectors and a lack of a Pharmacovigilance Centre in the State of Kuwait

Some 44.6% of the interviewees suggested that the control over the medical effects of the pharmaceutical administration process in patients is insufficient. They suggested that the main reason for the weakness in control is the lack of a Pharmacovigilance Centre in the country. Therefore there is a lack of specialized organization to monitor and follow up the effects of drugs after the completion of registration and the licensing process and a lack of continuing control to examine if a drug has any adverse effects on the patients. Therefore it was proposed that the establishment of a Pharmacovigilance Centre in Kuwait is needed to improve the control over drugs, especially in the private sector.

### 6.8.1 Definition of pharmacovigilance

It is the case that even though drugs are extensively tested on animals and other clinical trials on humans are carried out, unfavourable reactions may not be noticed unless they are experienced by many people during the use of the drug over time. Therefore it is very important that the safety of all drugs is examined all through their marketed life – this is known as pharmacovigilance (MHRA, 2010).

Pharmacovigilance is therefore the process of determining the risks and benefits associated with drugs so as to access the required action to use them safely and effectively. This process normally involves continuous examination of drugs to recognize any adverse effects or changes in previously identified effects of the drugs, and also the resultant outcome of any action taken on the drug. This branch of pharmacy can educate health professionals and consumers of the drugs, about their nature and effective usage, and this information about the drug helps ensure the safe and efficient use of drugs (WHO, 2002).

Pharmacovigilance with a larger population is also needed because although drugs undergo clinical trials, they are often tested only on small population sizes relative to the population size they are prescribed to during the medicines lifetime.

This means that previously undetected side effects may emerge. Drugs that cause severe adverse drug reactions must not only be identified but they must also be removed from the Health Care System and the market (Executive Agency for Health and Consumers, 2009). The surveillance of the safety of a medicinal product during its life on the market is extensively regulated by the major health groups across the world, such as the FDA in the USA, WHO in Sweden and the EU who have in place detailed directives and regulations (MHRA, 2010).

There are many sources of information which can be introduced within a Pharmacovigilance System, and these include reporting from healthcare professionals, which is usually specific to checking for adverse drug reactions. Other sources of information which are monitored, include clinical trials and epidemiological studies; other published medical literature, medical information from companies who manufacture the medicines, statistics on populations, information from within Health Care Systems and information on pharmaceutical consumption (SUKL, 2010).

### 6.8.2 Risk and benefits of Medicines

The clinical and side effects of medicines can be good as well as bad. When drugs are suggested by doctors, they should prescribe them after assessing the changes it causes in terms of adverse actions compared to the cure it provides. Any drug should be consumed only when the expected benefits override the possible risks from it. Consideration should also be given to the possible effects the drug will have on the patient after its consumption is stopped. However there is no accurate determination in the form of quantitative analysis of the severity of the potential risks and the benefits from drugs (MHRA, 2010).

Drugs are considered safe and secure only when harmful reactions are minimal compared to the cure associated with the medicine. However drugs by their very nature always carry the possibility of adverse reactions but still, it should not be neglected that the majority of individuals do not experience serious side effects. Medicine labels or the associated information sheets list the possible side effects for the medicine for its informed usage by consumers (WHO, 2002).

While prescribing the drug, health professionals should take into account its effect on a person's quality of life compared to risks from the drug, typical minor disorders include coughs, headache and muscle strains; these are often considered acceptable but if they are providing discomfort the symptoms it can be treated using effective over-the-counter (OTC drugs). OTC drugs can have wide safety margins when taken as prescribed. But serious or life-threatening disorders like heart attack, stroke, cancer, or organ transplant rejection are obviously considered highly important safety concerns and should be noted for their benefit–risk outcomes (Tarloff, 2007).

General risks associated with drugs include the possibility of not working as well as they should, problems that occur alongside the accepted cure, and chances of adverse reactions between the drug and a food, beverage or dietary supplement (FDA, 2011).

These are some of the reasons why a Pharmacovigilance Centre is needed for Kuwait – the Centre should focus on the assessment of benefit, harm, effectiveness and risk involved in the use of drugs, and promote their safe, rational and cost-effective use. A Pharmacovigilance Centre should aim to support information dispersal of information about drugs, educating the public about them, training the health care workforce to provide efficient services by providing clinical knowledge and practical experience. Also most importantly a Kuwait Centre would

expect to feed information into worldwide Centres such as the Uppsala Monitoring Centre in Sweden. However to join such a Centre would require the Kuwait Centre to have in place a standard set of procedures which are internationally accepted. It is for these reasons that within a NDP, there should be the capability of the KMOH to ensure control over side effects of drugs on the market (WHO, 2002).

Although the State of Kuwait is a small part of this world it has been affected by a number of difficulties which affect many other countries in world trade. However, for more than twenty years now, globalization, free trade increase, communication across borders, and the Internet have all caused a change in access to medicinal products and information reported about their use. Included in this are problems of the illegal sale of drugs by non-professionals, and abuse of these drugs through access over the Internet.

Difficulties that have increased are self-medication by the public, who although they may not be able to interpret or find accurate information, they sometimes self-medicate anyway. Irrational drug prescribing and use, although it may be dangerous, can be quite wide-spread and the manufacture, sale and delivery of counterfeit medicines are increasing. In addition the use of traditional drugs, outside their traditional use or in combination with other drugs, including herbal drugs, can cause a potential for adverse drug interactions. It has been suggested that pharmacovigilance should be applied to these situations; however these occurrences are normally beyond the confines of detecting new safety concerns (Meyboom *et al.*, 1999). It is suggested however that under the structures developed in the NDP, these should allow the development of a Pharmacovigilance Centre which given some development time could become a partner in a wider international Centre in the future.

Apart from helping to monitor the adverse drug reactions in Kuwait, the benefits of pharmacovigilance also include its use in drug regulation, clinical practice and international health.

With regards to drug regulation, arrangements to monitor drugs provide a basis on which national drug safety can be established, and this in turn can lead to an increase the confidence of the public in the medicine. The place of pharmacovigilance and drug control is linked into earlier clinical trials, during drug development, the safety of synthetic and complementary drugs including traditional drugs, vaccines and other biological drugs such as herbal, and overall is part of the lifetime monitoring of medicines as long as they are prescribed (WHO, 2002).

Currently the Drug and Food Control Administration of Kuwait is responsible for the process of monitoring drug safety in Kuwait, but because of limited structure and trained and full-time health professionals for this work, they often follow the reports of the USA Food and Drug Administration (FDA) without relying on their own studies. It is suggested that this could be dangerous because sometimes there are epidemics and diseases present in Kuwait that do not exist in the USA, or vice versa. In the future the setting up and operation of an efficient Pharmacovigilence Centre is likely to require the cooperation between the Drug Control and Pharmacovigilance Departments where it is likely to be for each Department to support the other by provision of the required expertise and data, so strengthening the control over pharmaceutical products and leading to the success of the monitoring process.

It is proposed that the Health Professionals in Kuwait should understand that drug monitoring is an important skill for a pharmaceutical professional in pharmacy practice. Therefore the degree to which pharmacists are informed about pharmacovigilance, and therefore they need to study the practice accordingly, as it can have an impact on the overall quality of health care delivery. Education in drug safety and a successful exchange of information between national centres, their

coordination, and linking pharmacovigilance to research and health policy are likely to have an important place in increasing and enhancing health care delivery (WHO, 2002).

### 6.8.3 How to monitor the safety of licensed drugs

Licensed drugs are evaluated for their safe and secure nature through using various information sources including clinical and epidemiological studies, WHO publishing, spontaneous Adverse Drug Reaction (ADR) reporting schemes, global medical literature, regulatory organizations, morbidity and mortality databases. Information then obtained is evaluated to determine the side effects from the drug, any possible reactions in certain individuals, probable adverse behaviour expected in certain situations, frequency of bad effects and their severity. Information when analysed should help to determine the safety of the drug and specify the control over the drug's use, like the changes required in providing marketing authorization or applying certain dosage changes, restricted usage and warning indications (MHRA, 2010).

From the information found during this research study, it has been possible to extract suggestions which can help in minimizing the risk of licensed drugs, and solving this issue in the State of Kuwait includes:

a) To continuous update of the product information or information label, specifically mentioning the warnings regarding the drug.
b) Removing the drugs that have questionable side effects from the OTC drug list, or making variations to the legal status of the drug, or making the drug prescription-only.
c) Limiting the indications for usage; in the case of a drug being of a hazardous nature, or the risks being greater than the benefits it provides, it can even be removed from the market, but only in exceptional circumstances (MHRA, 2010).

There are various ways in which Adverse Drug Reactions can be reported. One example of these systems is the yellow card scheme in the United Kingdom (UK) operated by the MHRA and Commission on Human Medicines. It receives reports of adverse drug reactions, or events that may be suspected to be adverse drug reactions, not only from health professionals such as doctors and nurses, but also from patients. In turn this can provide early warning to these groups of any adverse effects that drugs are found to have (MHRA, 2013). Countries such as the United Kingdom, New Zealand and the United States of America also have active surveillance programmes that use records and prescription event monitoring systems to collect data on drugs (Coulter, 2000).

Returning to Kuwait, from observation and discussions with the health professional interviewees during the PhD study (2012–2015), it is suggested as a result of this research; that the KMOH should support the establishment of a pharmacovigilance centre in Kuwait by taking necessary steps such as:

1. The KMOH could coordinate with the Kuwaiti Government (Civil Services Commission) to issue a law for establishing this centre in the country.

2. The question arises, where could the provision of an adequate and appropriate place for the centre, be located?. Academic Departments in universities and university hospitals are ideal for pharmacovigilance because it can easily be linked with the clinical, pharmacology and epidemiology departments. Such a location for the centre would be ideal for peer review of any adverse drug reactions that may occur, as there is access to experts, and this could improve the efficiency of the process. However any access to information on medicines would have to be kept confidential and agreements reached that this information would only be used through correct channels. This could mean that an advisory panel could be created. Any general educational information obtained in these centres could be incorporated into undergraduate and post graduate education programmes, but again specific information would only be available through agreement, but it would

lead to establishing a good knowledge base among new health care professionals (WHO, 2002).

National pharmacovigilance centres have played major roles in promoting drug safety and this is possible because many of these centres are based within hospitals, medical schools, poison information centres and also drug information centres, as opposed to being confined to a separate regulatory authority (Coulter, 2000).

Furthermore, health professionals are more likely to feel comfortable in reporting any adverse drug reactions to their academies or hospitals as they may feel that the familiar environment would be more likely to analyse any reports.

Finally, feedback on cases, support for experts and academic detailing can be better achieved under circumstances where pharmacovigilance centres are established in academia or hospitals (Soumerai *et al.*, 1990) (Davis *et al*., 1995).

3. The provision of all the necessary requirements for the pharmacovigilance centre, such as a trained and qualified health professional team, powers and authority to practice their work, participation, electronic links (not presently available in Kuwait) with the necessary health areas and the cooperation of other public health areas (e.g. Hospitals, Health Clinics, Food and Drug Control Administration, Drug Inspection Administration, Dasman Diabetic Institute and Kuwait University) to support this centre in providing the necessary data, research and information relating to the registered drugs and morbidity due to adverse effects. The establishment of committees comprising these health bodies is also needed to ensure continued control over drugs on the market.

4. The provision of governmental financial support for this centre to make savings in the national budget – in 1999, pharmaco-economic studies found that governments can spend considerable portions of their health care budgets on covering the costs of adverse drug reactions (White *et al.*, 1999).

5. In the larger scheme of development in the future Kuwait can consider working towards joining the Uppsala Monitoring Centre (mentioned above), as Kuwait is not a member of this centre at the moment. The Uppsala Monitoring Centre (run by the University of Uppsala) in conjunction with the WHO manages an international database of adverse drug reactions, based on reports received from national centres. It has been instrumental in establishing standardized forms of reporting by all centres involved, and has allowed good communication internationally to promote identification of signs, symptoms and signals (Olsson, 1998). The Uppsala centre also has created and provides training courses for health professionals about pharmacovigilance and provides suggestions and recommendations to the countries involved to improve their work, which may be an option for Kuwait in the future.

6. To communicate with health care professionals and patients to collect relevant and vital information about the drug, its effects, possible harm and other queries – with accuracy, in a timely manner and in suitable settings for both patients and health care professionals.

As an indicator of how there can be successful interaction between the medicines regulators and the health professionals, the MHRA in the UK use various ways; to include, specific drug hazards are sent to all doctors and pharmacists by post or electronic mail describing the urgent warnings; Patient Information Leaflets (PILs) and Summaries of Product Characteristics (SPCs) for medicines are continuously updated; safety alerts are published through the MHRA website, and a drug safety bulletin is published for the latest information on drugs (MHRA, 2010).

7. To make contact with a number of organizations involved in worldwide drug safety monitoring, such as the WHO, to gain the benefit from its experiences.

6.8.4 The WHO suggested some of the basic steps which should be taken when setting up a Pharmacovigilance Centre

Within the WHO, the quality assurance and safety team recommends that countries aims to close gaps between the beneficial potential that essential drugs may have, and the actual real world reality of people for whom drugs may be unavailable due to them being unaffordable, or they are unsafe or not correctly used (WHO, 2010).

The WHO outlines some of the basic steps which are generally needed when setting up a pharmacovigilance centre. Firstly, contacts should be established with health authorities and other institutions on a local, regional and national level. Furthermore, contacts need to be established with groups that work in clinical medicine, pharmacology and toxicology departments and they need to be made aware of the importance of pharmacovigilance. Once this has been established, there needs to be a system, potentially through a standard form, which can be distributed to medical departments so that data can be collected, along with information material for health care professionals which highlights the aims and methods of the new pharmacovigilance system.

Therefore the evidence suggests a Pharmacovigilance Centre should be created in Kuwait, and this means that there is a need for trained staff, development of database capability, a bibliography through a library and other aspects of developing a Centre of Information, in order that the Centre could provide information for health professionals on a continuous basis.

Staff involved within the centre should be of a certain educational level and trained with regard to attaining knowledge on pharmacovigilance. This would be particularly relevant to data collection, verification of data received, being able to; code any adverse drug reactions data received, to code drugs/medicines, to assess each case individually with regard to cause, the detection of signals and symptoms, and finally to assess the management of risks. Within the Pharmacovigilance Centre there must be an established database that is able to process all of the information collected.

In order to disseminate the information it is important that a system of communication is established, which can take a number of forms from written notification of findings on a regular basis, to holding or contributing to meetings with health professionals in medical organizations. In addition information on the principles of pharmacovigilance can be openly discussed, to provide knowledge for those new to the principles and can give assistance in their understanding and the demands that operating as Centre can make. The advantages for Kuwait in reporting of adverse drug reactions should also be promoted; which can take a direct form, or can be done through medical journals, professional publications and other forms of communication.

In addition, a countries centre should maintain contacts with other Centres and Institutions that work in pharmacovigilance, especially the WHO Department of Essential Drugs and Medicines Policy, and also the Uppsala Monitoring Centre (WHO, 2000).

Although ideally all adverse drug reactions would be reported, there are often problems when running a Pharmacovigilance Centre. One of the major points is the level of reporting, which tends to start off successfully in terms of reporting numbers, but with time tends to reduce considerably. One reason given for why professionals may not report all adverse drug reactions may be apathy and an overall lack of awareness among prescribing professionals, and when the Centre is in place under the NDP structures, the KMOH should be aware that this is likely to happen. Furthermore, although adverse drug reactions seem to be reported in a spontaneous manner – the level of reporting does drop off with time and it is usually the case that following reminders, meetings or advertising programmes the level of reporting can increase considerably (Dikshit, 2008).

In conclusion the establishment of a Pharmacovigilance Centre in the State of Kuwait is likely to develop and improve the health care system through:

1. Promoting control and monitoring adverse drug reactions, medical errors and counterfeit drugs across the public and private sectors.
2. Developing a national disease control programme and increasing the monitoring of ADRs.
3. Undertaking the assessment of risk and options for risk management.
4. Identifying and classify any issues relating to patients taking drugs in Kuwait.
5. Helping to improve supply management and supporting the CMS and private companies in the selection and purchase of drugs.
6. Improving the Essential Drug List (when one is developed) by determining the quality, safety and efficacy of drugs for Kuwait.
7. Saving the national budget by reducing the expense of covering the costs of adverse drug reactions, and promoting the KMOH's choice of drugs.

### 6.9 Spread of irrational use of drug in the State of Kuwait

Some 86% of interviewees strongly advised that irrational drug use is a serious issue in Kuwait, especially the irrational usage of antibiotics, hormones used for the sport such as for body-building and the use of sexual medicines. In terms of the State of Kuwait, a large part of the problem revolves around self-medication. This leads to irrational use (sometimes abuse) of antibiotics, psychotropic, slimming, sexually related drugs and herbal drugs, and this area should be addressed under the guidelines of pharmaceutical therapy and focused on in the NDP. As a result, the KMOH should consider, as part of the NDP, increasing the education to the public by increasing access to health education programmes for the media, in schools and in public areas. In addition they could encourage the establishment of

health education conferences and seminars that warn the population and health professionals of the irrational use of certain medicines and describe the health disadvantages of this practice.

Overall it is suggested that the KMOH as part of the changes which are likely to be envisaged in the NDP, should re-examine the legislation related to the control of prescribing and dispensing medicines in both the public and private sectors.

### 6.9.1 The irrational use of drugs

As part of the many areas which make up a NDP, the examination of rational prescribing dispensing and use are essential when establishing the NDP. The essence of rational drug use is that patients receive medications appropriate to their clinical needs, at an appropriate individual dose, for an appropriate time period and at the lowest cost to themselves and the community (WHO, 1987). It is, however, estimated that over 50% of all medicines worldwide are prescribed, dispensed or sold inappropriately, while at least half of all patients fail to take their drugs correctly (Hogerziel, 1995). These were very worrying figures and added to this, it is estimated that only one third of the world's population has access to Essential Medicines, which contributes greatly to this problem (Ford, 2003).

It has been proposed during the research for this study that the Health Care System in Kuwait suffers from many issues that cause and increase the irrational use of drugs, such as; there is a considerable lack of knowledge among prescribers and patients, lack of guidelines and standardized treatment regimens, and weakness of control regulation over the private pharmaceutical agents, companies and pharmacies, all of which contribute to this problem, which is considered to be a problem particularly in Developing Countries. The consequences of irrational use are often devastating and not only jeopardize the health of patients, but also increase the level of resource waste and financial

burden placed on a Health Care System. As a result, support groups such as the International Network for the Rational Use of Drugs (INRUD) (established 1989) were set up to design, test and disseminate effective strategies to improve the way drugs are prescribed, dispensed and used, with particular emphasis on resource-poor countries (INRUD, 2003).

These policies are applicable to every nation, although the developing world is a key target for the future. The aim of this section is to discuss the causes and consequences of irrational drug use in some detail, to focus on the strategies in use to resolve the problems and relate this information to the handling and solving this problem in Kuwait.

### 6.9.2 Examples of irrational drug use in Kuwait

Irrational drug use can be found in a number of circumstances and can stem from the manufacturing process, consultation and use by the individual patient (Contact, 2006). One of the most common examples of irrational use in Kuwait is antibiotics (Antibacterial), which are often prescribed unnecessarily and this is suggested to be due to the lack of a clear antibiotics prescribing system. It has been proposed that there is also no control over and monitoring of the number of antibiotics prescriptions for each public clinic or linked to individual physicians.

As an example of where this can cause medical problems and is effectively linked into medical negligence is where a viral illness is present, and many of the physicians in Kuwait and especially those working in health clinics prescribe antibiotics for infected patients without taking a sample for a laboratory to run a culture test to ensure if the infection is bacterial or viral, or where they may prescribe at a dose that is too low to be effective (Chandy, 2008).

On the other side a Patient may be poorly educated in the importance of completing a course of the antibiotic in question, and so may not take the required dosage (WHO, 2000). These problems can lead to under-treatment of the initial infection and the development of resistant organisms, which can be a major problem, particularly where alternative agents are unavailable. The use of antibiotics which have a known resistance pattern in the population is also an example of irrational drug use (Lancet, 2010); but may occur where resources are poor or education is low (Barah *et al*., 2009). Anti-motility agents prescribed for diarrhoeal illness are another example of irrational drug use in the developing world. (See Figure below)

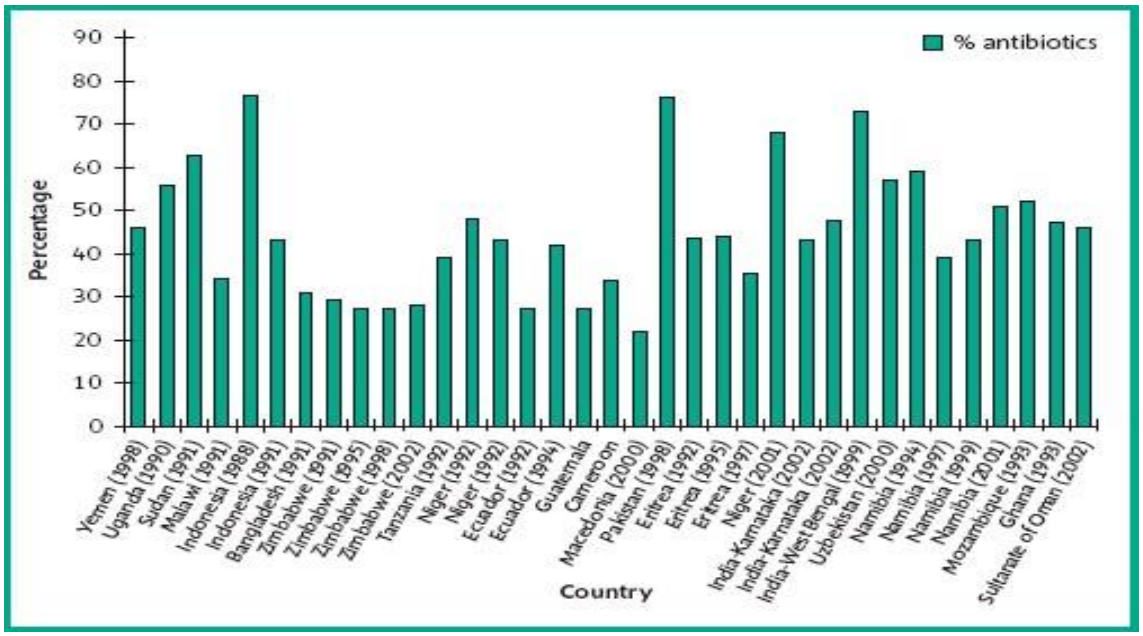


**Figure 6.7 Percentage of patients receiving antibiotics (adopted from WHO, 2004)**

Figure 6.7 shows data from a range of countries on antibiotic prescribing. On average, about 45% of the patients were prescribed antibiotics. However, in

Indonesia (1990), Pakistan (1998) and West Bengal, India, (1999) rates in excess of 70% were observed, and the prescribing patterns should have been questioned.

It is proposed that the clinical needs of the patient must be considered when prescribing drugs and their rational use, which often only occurs following a lack of adherence to available clinical guidelines or a lack of guidelines in the first instance (Chandy, 2008).

Another reason proposed in this study for the spread of irrational drug use in Kuwait is the non-compliance of some private pharmacies to the KMOH regulations and legislations, where they may dispense prescribed drugs (Antibiotics, Antihistamines, Sildenafil (Viagra) and Testosterone hormone) without prescriptions. Also it was proposed that some private pharmacists dispensed drugs which were not suitable for the particular condition or at an incorrect dose for the patient which can lead to serious consequences or health concerns.

Many countries have introduced a system of poly-pharmacy, but this form of dispensing can lead to problems, where too many drugs are prescribed at the same time for one patient. Often these medicines are prescribed without thinking about introducing the risk of drug interactions and increasing the chances of side effects in the patient. Often this reflects an uneconomical approach to prescribing and a lack of review of patient medications (some prescriptions may have been renewed continuously for years, without reference back to checking on the medical condition and despite the advice of the doctor and the consequences to the patient of inappropriate use, drug interactions and drug resistance). This can be a major issue in the developed world, particularly among elderly patients (Barah *et al*., 2009). Based on the information presented above, it is suggested that the KMOH should consider introducing a better structured adverse drug reaction monitoring system within the overall development of the NDP.

As indicated above self-medication by patients is a factor in irrational drug use, with individuals often taking medication that is out of date or not suitable for a particular condition. In some cases the patients had found the medication at home, either following an earlier prescription for a previous condition or had taken medication given to another individual (Barah *et al*., 2009).

During the structured discussions with the physician interviewees as part of the PhD study, self-medication was mentioned as one of the major causes of irrational drug use in Kuwait – it is indicated that many patients, especially elderly people, use self-medication, (due to lack of education) and uneducated parents. For example, some parents are reported to have used Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen for their children without consulting a doctor, to reduce a high temperature, even if the temperature was mild. Another important example of parents using self-medications, is the case of a child with asthma, and the parent had given an inhaled bronchodilator drug (Ventolin – an asthma treatment) for a child suffering from a cough because they thought that this medication would be useful for the treatment of coughing, even if the child did not suffer from asthma (Hutin *et al*., 2003).

As a result, a number of studies have proposed that rational drug use should also extend into patient education and monitoring of drug treatments in order to prevent such occurrences. An associated issue in rational use is the medical device in which medication is delivered to the patient clinically – which raises another topic worth considering as the part of a NDP which would deal with education of health professionals and the public. This example is the over-use of injections, which is rife in many developing nations. While injections may have a perceived placebo effect compared with a tablet in some populations, the risk of needle contamination, infection and ineffective drug delivery is increased and therefore alternative means of delivery should be prioritized where appropriate (Hutin *et al*., 2003).

Based on the examples provide by the interviewees and the literature, above, it is suggested that the KMOH should consider a programme which can provide advice to feed into the NDP which can help to solve the issue of irrational use of drugs and ensure public safety and support in develop and improving the Health Care System in Kuwait, as part of development and implementation of the NDP.

### 6.10 The lack of a pharmaceutical industry in the State of Kuwait

Some 83% of the interviewees (in Chapter 4) were in favour of developing a Kuwaiti Pharmaceutical Industry, because it can secure the country's medical resources by providing the availability of the medicines during emergency cases, epidemics and war, where a rapid influx of the required medicines may not be readily available from outside the country. It also increases and improves national sources of income and develops pharmaceutical technologies.

However Kuwait has a poor experience in the field of developing pharmaceutical industries; there is only one modest industry (KSPICO-Pharmaceutical Industry) and it is unambitious, where the medicines manufactured in this industry are generally only based on simple generic medicines (e.g. ointments, creams and tablets) and this industry receives most of its raw materials from India and China.

Kuwait is essentially like many developing countries and has a similar health status to many of them; for that reason it is necessary to study and review the importance, need, advantages and benefits of pharmaceutical industries for developing countries to understand the importance of this aspect, and how is it possible to realise benefits for the State of Kuwait.

According to recent statistics, developed countries contribute to their pharmaceutical industries more than they do to the development of defence and aerospace industries, and the research-based pharmaceutical industry is consistently financed, even during the periods of financial crisis and economic turmoil; however, the situation is the opposite in developing countries, thus underlining the importance of future investments in this area (IFPMA, 2014). Based on the estimations of the EU industrial scoreboard 2010, the majority of pharmaceutical companies are based in the US, Europe and Japan, with daughter companies having sprung up in developing countries (Spilsbury, 2014).

However many factors contribute to the presence of a pharmaceutical industry in developing countries and the existence of such an industry is associated with considerable financial investment into the economy. But the rewards in terms of better provision for the people of Kuwait and the views of the Health Professionals interviewed suggests that the development of its own industry, should be a priority in the not too distant future and the Kuwaiti Government should give attention to increasing investment in this area, and also encourage local and foreign investors to invest in the industry and for the government to provide all necessary assistance for them and create a basis for a suitable grounding for such projects.

### 6.10.1 How to ensure compliance between the pharmaceutical industry and NDPs?

NDPs set-out important guidelines for the use of drugs, they do not provide legally-binding commitments to the country, and therefore, have little legal power to ask companies to cooperate with them. NDPs have likely been drafted in this way as it allows a government pursuing a NDP increased flexibility to deal with implementation problems along the way, or to modify the approach.

After a NDP is completed, a country will have a better idea of what it requires from the pharmaceutical industry to achieve its aims, which may be to get essential

medicines to more than 90% of its population. However, knowing what is required is not the same as getting what is required, for which a country must talk to large medicine buying groups or the pharmaceutical companies themselves. Given that many countries have very large populations and very small public finances, expectations on both sides of the negotiating table could be widely disparate. Here, negotiation on a case-by-case basis has led to deals being reached between private companies and governments sourcing medicines, although in many cases agreements are not reached (Morgan et al., 2008).

As touched upon earlier, agreements between governments of developed countries, such as the UK and EU members, have been drawn up to establish fair pricing frameworks (UK Government, 2010). Such agreements could be replicated by other countries as they implement their own NDPs, and often groups of countries negotiate together for a better deal. Further good news for poorer countries is the rapid development of the generic drug market (i.e. in India) over the past 20 years, making off-patent drugs (many on the WHOs list of essential medicines) readily available at minimal cost (Morgan et al., 2008).

Given that governments are the largest purchasers of drugs, it is in the interest of the pharmaceutical industry to work with them to increase revenue and profits (Zadeh, 2013). However, drug pricing remains a highly controversial topic (Moynihan et al., 2002), and many senior politicians in the UK have called for the pharmaceutical industry to be nationalised so that the best treatments can be made available to all regardless of the cost. In reality, however, the development of new drugs costs many billions of dollars, and the fact that private corporation buy those products reduces the incentive to immediately drop prices to more affordable levels. The cost of investment in new medicines is also the most commonly cited reasons as to why drugs cannot be given away to the developing world. The deals between third world governments and pharmaceutical companies should be

considered on a case-by-case basis with the aim of getting medicines to the greatest number of people possible.

In future, it is possible that the cost of drugs will be fixed and related to other economic measures in a country -such as capping maximum drug expenditure by a country to a nominal percentage of GDP(Good Drug Practice), with the company fulfilling the rest of the cost (Shajarizadeh and Hollis, 2015). In this way, countries will be more likely to invest in the healthcare of the citizens knowing that its budget is protected for other requirements and that the international community is trying to help.

Long-term business confidence is greatly aided by stability and predictable outcomes. In this light, the effective execution of a NDP – which orders and pays for drugs periodically – ensures pharmaceutical companies are treated fairly, helping them work together with government representatives professionally and routinely. Indeed, it must be noted that both parties should be looking to make a deal and work together, which in the long-term will help establish standard worldwide networks for drug manufacture, purchase, distribution and use.

### 6.10.2 The importance of pharmaceutical industries for developing countries

The importance of pharmaceutical industries to a country like Kuwait is a highlighted by the effects of this sector of the economy on the health of the country's population and also on global health. A pharmaceutical industry is capable of substantially improving people's lives – through small and large discoveries in the pharmaceutical arena and contribute to considerably elevating life expectancy as well as contributing to better life quality of the population of the country (Jacobsen & Wertheimer, 2009). For instance, with the aid of vaccines it became possible to eradicate smallpox at both regional and global levels and eliminate measles and polio at the regional level. Presently, with vaccines, it is projected that overall the lives of approximately 2 million children are saved

annually. In Africa, recent success of pharmaceutical industry development has been reported by the WHO which it is estimated will prevent approximately 3 million malaria deaths and reduce the number of disability cases by one million (WHO, 2005).

In addition, immunization campaigns have reduced measles deaths by 91%. Among other factors highlighting the importance of drug industries, it can be stated that since the beginning of the 20$^{th}$ century scientists have been able to discover and further develop nineteen antibiotic classes, resulting in the possibility of treating thousands of infections and saving millions of lives. The pharmaceutical industry, through a series of medical discoveries, was able to discover 20 varied antiretroviral techniques for treating HIV/AIDS – essential for epidemic control in developing countries. With the introduction of national drug industries, developing countries will be able to produce their own drugs against diabetes, cancer, HIV/AIDS and malaria (Jacobsen & Wertheimer, 2009).

At present all the medicines mentioned above (vaccines and antibiotics) and other drugs are imported to Kuwait, which does not manufacture any of these within the country. If it were the case that an Industry could be developed, in the first instance it would most likely be based around the production of generic medicines and possibly also producing medicines as a national subsidiary of one of the multinational pharmaceutical companies. But with time it may be possible to expand into the development and production of novel drugs. In first case, the development of a pharmaceutical industry would support the State at least in terms of self-reliance in the supply of necessary common medicines, ensuring the provision of these medicines at all periods and especially in emergency situations.

When looking at the state of health of the population in developing countries and its effects on the economy, it can be indicated that the introduction of a

pharmaceutical industry in these countries manifests two types of social benefits. First of all, it becomes possible to improve both mental and physical wellbeing of every member of society. Additionally, it lowers the costs of medicines and possibly hospitalization and other types of health care (WHO, 2005).

The likely future prosperity of this sector in Kuwait should result in savings in the national health budget. As mentioned in Chapter 4, in 2014–2015 the KMOH spent 700 Million USD on the purchase of drugs from abroad, so it is certain that the presence of pharmaceutical industry If an industry does develop in Kuwait it is likely it would reduce the proportion of the budget spent on high-cost, internationally shipped and insured medicines, and instead use inexpensive manpower within the country.

### 6.10.3 Why the State of Kuwait needs the pharmaceutical industry

The State of Kuwait should invest in its own pharmaceutical industry for a number of reasons; one of the primary reasons is the necessity of removing drug monopolies, which are a fundamental issue in accessing drugs and draining the budgets of developing countries. The Kuwaiti Government can act on reducing costs of medicines by developing and improving investment in this field.

The effects of drug monopolies on developing countries were explored in a recent publication by R. Hellerstein. The paper focused on the assessment of antiretroviral drug (ARV) prices in Africa, where the pharmaceuticals market financing is greatly affected by foreign pharmaceutical companies. Two types of data were obtained; the first group included countries with no widespread availability of antiretroviral drugs and for this reason prices were dictated by monopolistic companies. These countries included Uganda, Tanzania, Rwanda, Kenya and Ethiopia. In contrast, the second group was formed by developing countries with availability of ARV drugs, and this group comprised Cameroon, Thailand, India and Brazil. Due to the presence of a national pharmaceutical

industry as well as foreign companies, prices were able to be set, based on the result of competition among companies (Hellerstein, 2011).

Therefore for these countries where a monopoly exists (which is also likely to include Kuwait) the need is both financial and to access drugs appropriate for the countries needs. This problem is connected with the presence of monopolies in the corresponding markets. As a result, expenditure on drugs was determined as a considerable proportion of the total health costs recorded in developing countries. Consequently, access to the required treatment is in considerable correlation with affordability and availability of medicines.

According to the estimations of the WHO, 1/3 of the population in developing countries is not able to regularly obtain essential medicines (WHO, 2005). The WHO also stated that introduction of pharmaceutical industries in developing countries should promote distribution of medicines in the following ways:

1. Rational selection and employment of medicines.
2. Acceptable prices for medicines.
3. Sustainable involvement of financial resources from abroad.
4. Formation of reliable health systems.

In terms of the factors outlined above, it can be stated that reduction of drugs prices should be the most important issue addressed by the implementation of pharmaceutical industries. Thus, the WHO determined that investment in such industries in developing countries should reduce margins, taxes, and tariffs, along with the development of pricing policies. Competition among pharmaceutical companies should also increase what will lead to multi-source product availability (WHO, 2002).

Finally, it is clear that Kuwait should invest in its pharmaceutical industries and companies to become independent from the foreign pharmaceutical companies that dominate the market.

### 6.10.4 The advantages and benefits of the pharmaceutical industries for the State of Kuwait

In addition to becoming independent from foreign companies, reduction of prices for the most important drugs and an increase in the life expectancy of the country's population, the introduction of a pharmaceutical industry is also associated with a range of other advantages and benefits for Kuwait. The most important of these are associated with the economic impact of pharmaceutical industries. This sector is robust and was proved to be a highly important aspect of the economies of industrialized countries. It also is increasingly manifesting itself as an intrinsic part of the economies in the developing world (Cook, 2015).

Looking at the current investments in developing countries, it can be stated that the pharmaceutical industry research and development sectors of the economy in China and Brazil were estimated to be 74 billion USD and 134 million USD respectively in 2008 (Shadlen, et al., 2013).

The pharmaceutical sector can also have a considerable positive impact in developing countries which sometimes exhibit a lack of innovative production capabilities, via the diffusion of technology allowing substantial improvements in the manufacturing of original drugs and generics (Shadlen *et al.*, 2013).

The activity of pharmaceutical industries can also have a considerable positive impact on a country's economy. In the majority of cases, the economic impact is observed in the form of financial investments in the research and development of new drugs as well as their manufacturing. Additional positive effects include

improvement of conducted academic research and support for the formation of companies that conduct the development of new drugs and the production of existing ones. The research-based drug industry is highly active in developed countries. Thus, in countries such as the US, UK, France and Japan, billions of US dollars are invested in pharmaceutical companies. These investments give a considerable boost to the economies of the corresponding countries. Nevertheless, development of drugs is not only connected with their production. For instance, a country may have low research and development activity, compared with the production of drugs, while the activity of other countries may be focused on drug development rather than on their production. Consequently, State of Kuwait should establish the activity that contributes the most to their economies and attract the required financial resources (Schweitzer, 2006).

As outlined above, the pharmaceutical industry substantially contributes to the formation of new work places for health care professionals in Kuwait, encouraging them to work in the private sector and reducing pressure on the Kuwaiti Government to provide jobs for new graduate health care professionals in the public sector.

This beneficial contribution was observed in both developing and developed countries to differing extents. In 2006, it was estimated that pharmaceutical industries in China employed 1.3 million people. Additionally, 92K and 25K of people were employed in Brazil and Turkey respectively, and 4.2 million were employed in India, highlighting the intensive development of this region (Kuanpoth, 2010).

The pharmaceutical industry is able to provide high-skilled job opportunities via direct employment and also promote the creation of workplaces not directly connected with the production of drugs. Knowledge dissemination throughout the economy presents another beneficial consequence of pharmaceutical industry development. For instance, people employed in the pharmaceutical industry in the

majority of cases are exposed to new processes and techniques as well as receiving additional qualified training. These trends substantially contribute to the formation of a trained workforce with the possibility of employees changing their workplace or starting a new company, something that would help foster the economic development of the whole country (Kuanpoth, 2010).

In the discussion above it was indicated that pharmaceutical industries were highly important for Kuwait and the most important advantages and benefits are summarized here:

a. Increase and make savings in the national budget.
b. Reduce the proportion of high-cost drugs.
c. Ensure the availability of necessary drugs and secure access to essential drugs during wars and emergency cases.
d. Improve availability of statistical studies and future planning for health care services.
e. Develop the national investment and economy.
f. Improve the quality of life of the population, and increase the life expectancy of the country's population.
g. Reduce the effects of monopolies imposed by international companies.
h. Contribute to increasing new work places and providing job opportunities for health care professionals.
i. Participate in the transfer of technology to the country; recent studies suggest that advanced technology transfer is of paramount importance to the economic development of all countries.
j. Increase the acquisition of information, equipment, experience and innovative processes.

Based on the advantages and benefits mentioned above, it is suggested that the Kuwaiti Government should support the development of this sector and follow the successful examples of the Gulf States (Saudi Arabia, Oman and United Arab

Emirates) that have preceded Kuwait in this area, and that they take several measures contributing to the implementation of the pharmaceutical industry, by:

1. Encouraging and urging of private companies and investors to invest in this economic action plan and provide all necessary facilities for them.
2. Participation of the Kuwaiti government to invest in this area by allowing the Kuwait Investment Authority (KIA) (which is considered the fifth-largest sovereign investment fund in the world with assets equal to 592 billion US dollars) to invest in the pharmaceutical industry, to diversify the income sources of the State and ensure health security.
3. Establishment of an official website dedicated to this aspect, which provides all the necessary information, regulations and legislations, data and requirements for this plan. It should be a source and reference for local and international investors, companies and agencies interested in identifying and viewing such investments in the country.

### 6.11 The lack of a Linked Electronic System in the public health sector

During the PhD Research Program visits were carried out to the Public Health Areas of the; Drug and Food Control Administration, CMS Administration, Drug Inspection Administration, Drug Release Department in Kuwait International Airport, 10 public hospitals and 2 health clinics (Period of visits, 2012–2015), where informal ans structured discussions with professional health care staff were carried out and in addition observation of the nature of the work and its operation in each of the Administrations and Health Care Centres, was carried out. This research was approved by the Ministry of Health in Kuwait.

Throughout these discussions and particularly through observations it was clear that the, communication, method of working, collection of data, recording visits and medicines inspector visits in the public sector suffers from a lack of an electronic system to link different areas together, and that receipt of medicines at the airport and port would greatly benefit from electronic recording of all stages of medicines management within the KMOH, whether by an internal e-link inside the Administration, hospital or health clinic itself or external e-link between theses health areas. In spite of the provision and presence of computers in each department and supervision of these health areas, the KMOH has not provided an e-link system (until now).

The equipping of a e-link system should include all the pharmaceutical administrations of the KMOH and the pharmacies in public hospitals and health clinics –not having an e-link can cause many issues (mentioned later) that impact negatively on the development of health services and this would not support the implementation of a NDP in Kuwait.

In this section, the difficulties created by the lack of an e-link system in the KMOH health areas was observed during a visit to the health areas as part of the PhD study. The visit was designed in order to try to understand the limitations relating to the work of the KMOH, the possible solutions, and the advantages and benefits that can be obtained from establishing an e-link system in Kuwait.

The public health areas that most require the presence of an e-link system in their work process include:

1. Drug and Food Control Administration.
2. Drug Inspection Administration.
3. The CMS Administration and Pharmacies in public hospitals and health clinics.

### 6.11.1 The Absence of an Electronic Link System in Drug and Food Control Administration

It was found during the visits and in discussions with staff that the system of work in this Administration suffers from the lack of an e-link between the different supervisions and the departments, which is thought to cause hindrances in the following areas:

1. An increase in the time taken to complete routine tasks and delays in work practices, where the work is not completed as quickly as required
2. The accumulation of hardcopy files and papers and the difficulties of cataloguing with the possibility of loss or damage to their content.
3. Increasing need for porters to manually transfer the results of the analysis samples from the Laboratories Supervisions to the Registration and Release Supervisions.
4. The need for internal committees to enable the exchange of data between the supervisions.
5. Unavailability of additional electronic copies of drug registration files to use in case of loss or damage, specifically in the case of fire.
6. The availability to access and exploit information easily because all drug registration files since the establishment of the Administration have only been saved in paper form.
7. Limitations in the ability of the senior staff to follow, check and control work.
8. An increase in complaints from drug companies, agencies and suppliers because work is delayed, because the production of results and decisions is longer than it would be with electronic recording.
9. As above the limitations of using only paper copy has reasonably regularly prevented drugs suppliers obtaining early release for medicine shipments from the Drug Release Office in Kuwait International Airport because of the slow delivery of clearance from data supplied on licensed drugs. This occurs even though this office belongs to the same administration. Suppliers instead have often to gain clearance/ approval from the main Administration Offices, which are located far from the airport site.

The introduction of an e-link system would clearly lead to much faster, generally safer, and better communication between the Supervisions and Departments of the Drug and Food Control Administration and would therefore resolve the difficulties mentioned above. In particular the main areas to benefit from an e-link system would be between the Laboratories Supervision, Registration and Release Supervision and the Drug Release Office in Kuwait International Airport, which is likely to ensure sharing of all the necessary data and information between them (See Figure 6.8 below).

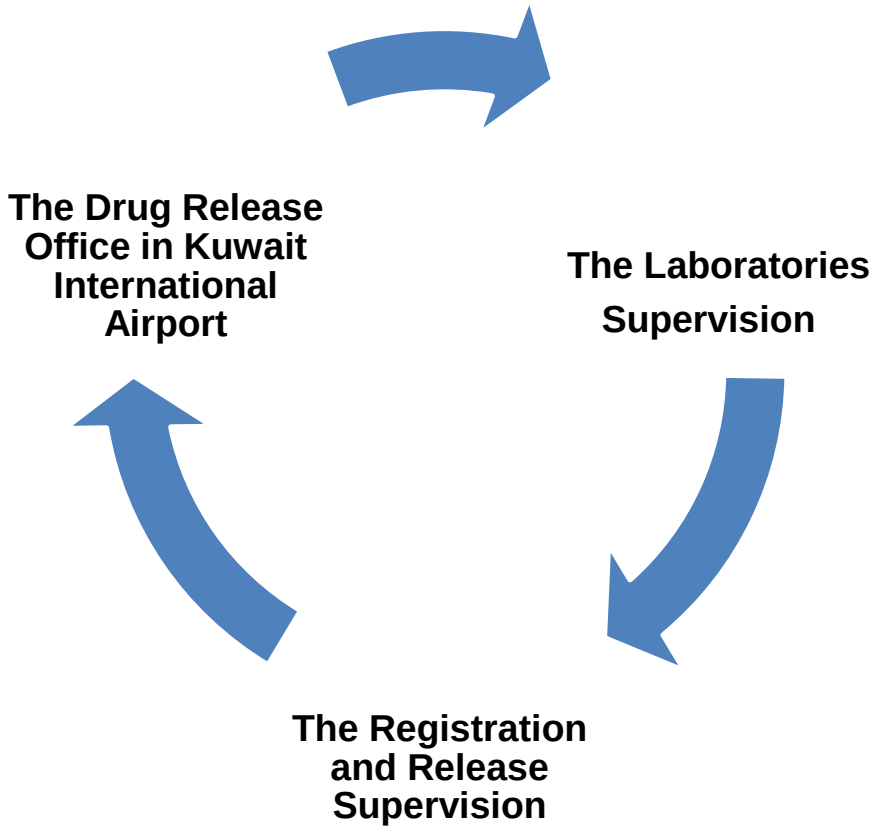


**Figure 6.8 The establishment of an e-link system between the supervisions and department of the Drug and Food Control Administration.**

The major advantages and benefits of improved efficiency and time saving from an e-link system between the Laboratories Supervision and Registration and Release Supervision would result from reducing the drug registration time; by providing data in the fastest time possible; helping senior staff (Supervisor and Head of Departments in both Supervisions) to follow, control and monitor the drug registration process and provide a more efficient file record system. The overall advantage would result from earlier decisions and release of the results from the registration process to companies.

As indicated above, one of the bottle necks is the communication on the initial receipt of medicines at the Drug Release Office in Kuwait International Airport and the main Release Supervision. An e-link system would improve the provision of all the necessary data (for all the registered drugs in Kuwait) at the Central Administration, and give a positive effect on the work involved in drugs release. As a result, pharmaceutical companies, representative agents and suppliers should not need to visit the distant main building of the Administration to get approval release for their shipments. In additions to time saving there would be a reduction in the cost of storage of shipments at the airport until clearance is agreed, and also there would be a reduction in the workload for Central Administration staff.

In addition to the need for an e-link system for this Administration, it is suggested that better communication with health professionals could be achieved if an official website for the Drug and Food Control Administration be set up. This could provide many benefits, including:

1. Being a reference for the pharmaceutical companies, investors, suppliers and local agencies by providing all the information relating to:

a) The registration requirements for pharmaceuticals, herbal medicines, veterinary drugs, cosmetics and food supplements drugs and medical devices.
b) The registration requirements for a pharmaceutical company's licences in Kuwait.
c) The necessary requirements for pharmaceutical advertisements.
d) Identifying and explaining the registration process.
e) The information related to drug pricing.
f) Enabling drug companies to submit the details for registration of drugs electronically (by email) and follow the registration process through the Administration's website without the need to visit the area.
g) Using the website for announcements of the latest Ministerial Decrees and new requirements relating to drug registration, licensing and advertising.
h) Using the website for announcements of the cancellation of drug licences in case of adverse effects of the drug being found.
i) Being a reference for health care professionals and the public, enabling them to access information about the traded and available drugs in Kuwait.

### 6.11.2 The Absence of an Electronic link System in Drug Inspection Administration

As mentioned in Chapter 5, the absence of an electronic system in the Drug Inspection Administration caused difficulties and has had a negative effect on the control of drugs in the Kuwait health system. Presently there is only a limited link between this Administration and the Drug and Food Control Administration. The process of data transfer (new registered drugs, latest drugs pricing and approved drug advertisement) from the Drug and Food Control Administration to this Administration is presently carried out manually, and this basic method does not help the inspectors in updating the existing data and identifying any irregularities in an accurate manner.

To resolve these issues and improve the work of drug inspection in Kuwait, and specifically the inspection of traded drugs in private pharmacies, it is suggested that an e-link system between the Drug Inspection Administration, the Registration and Release Supervision, the Drug Pricing Department and the Committee for Drugs Advertisements (which belongs to the Drug and Food Control Administration – see Figure 6.9 below) is set up as one of the important links within the NDP to ensure:

a. Continuity access to all a necessary data at the right time.
b. Reduction in the sale of unregistered drugs and drugs that need a renewed license.
c. The drugs in the private sector are sold according to the prices set by the KMOH.
d. All drug advertisements are controlled, by identifying if the product is licensed and the content of the advertisement matches what is approved in the licence.
e. All private pharmaceutical companies are registered with the KMOH.


**Figure 6.9 The establishment of an e-link system between the Drug Inspection Administration and the pharmaceutical parts of the Drug and Food Control Administration.**

6.11.3 The Absence of an Electronic Link System in the Central Medical Store Administration and in pharmacies in public hospitals and clinics

One of the main functions of the CMS Administration is distribution of drugs to all pharmacies in public hospitals, health clinics and health centres (6 general hospitals, 9 specialized hospital, 13 specialized health clinics and 93 general medical clinics) in the State of Kuwait (see Chapter 5).

The process of drug distribution from the CMS to the public pharmacies is based on contact between the CMS and the Central Pharmacies of the KMOH, where in each Health Area there is a Central Pharmacy supervised and responsible for the work of public pharmacies affiliated to its area of work. When a public pharmacy

needs a new drug order, they ask the Central Pharmacy to supply the required quantities of drugs, and then the Central Pharmacy sends the request to the CMS to prepare the required medicines and distribute them to the pharmacy.

The present communication is between the CMS and Central Pharmacies and is done through committees, KMOH postal mail and phone. This can be a unsophisticated method which is slow and therefore causes delays in the drug distribution process, negatively affecting access by the pharmacies to the required medicines in a timely manner, and often leading to problems in availability (e.g. of Vitamin D, some brands of antibiotics and statins) for the patients.

During the PhD study and through interviews and discussions, many pharmacists working in public pharmacies and CMS emphasized that this communication system doesn't help the CMS to effectively distribute drugs to all the public pharmacies in the required time.

It was again emphasised that the e-link system between the CMS, Central Pharmacies and pharmacies in public hospitals and clinics should provide the support to solve these problems and regulate the process of drugs distribution and ordering.

The advantages and benefits that could be obtained from an e-link between these Health Areas are:

1. Providing information on stored drugs (amounts and use by dates) (through an electronic database) in the public pharmacies in Kuwait to the CMS, which helps the CMS to determine the priority of drug distribution for pharmacies according to the needs.

2. Supporting the CMS to control and monitor drug consumption in each public pharmacy.
3. Reducing the delay in drug distribution to the pharmacies.
4. Ensuring access to the required drugs for each public pharmacy.
5. Supporting the CMS in identifying and providing the appropriate medicines by analysing the electronic database from the e-link system.

In addition, the e-link system would help to develop and improve the work of drug dispensing and storage of prescriptions and patient files in public pharmacies, where the lack of this system causes concerns such as:

1. After completion of dispensing in the pharmacy (e.g. in Alsabah Hospital), hard copies of all the medical prescriptions and patient files are sent to be stored in the Archive Department. This Department is located outside the hospital, because of lack of space to keep them on site, and also the lack of an e-link system. This requires a daily effort to transfer patient files and prescriptions manually from the Alsabah Hospital pharmacies to the Archive Department, and causing delay in access to the necessary information if it is required again. In the case of any emergency (e.g. a fire) all the stored data could be damaged or lost, and there are no additional copies to replace them.
2. Lack of annual statistical studies for the number, quantities and types of dispensed prescriptions, due to unavailability of electronic data.
3. Because there are no formalised records, some patients may take the same drugs from different hospitals or health clinics at the same time, which can be dangerous for their health and life as they make take over doses or give the additional medication to someone else (self-medication) and causes wastage in the KMOH budget.

To alleviate the problem above it is suggested that the KMOH resolve these issues and develops the access to additional information in their pharmacies by setting up an e-link system between:

a) The pharmacies in public hospitals and health clinics, to prevent patients (especially patients with chronic diseases) from acquiring the same drug from different public pharmacies in the hospital itself or from different hospitals and health clinics at the same time. This is safer for the patient and makes savings in the KMOH budget.

b) The pharmacies in the same hospital, to share and exchange the dispensed drugs and other data between them.

c) The pharmacies and medical clinic (physicians) in the hospital, to reduce medical errors and to ensure that physicians have enough information (types, brands and amounts of drugs) about the available stored drugs in the pharmacies, and to ensure a good prescription.

d) The pharmacies and the Central Pharmacy in each Health Area, to save the time in ordering drugs and increase the control over dispensed drugs.

e) The Central Pharmacies and CMS Administration, as presented above.

In summary the discussion in this Chapter concentrated on the interview results and the information and data collected from the KMOH during the PhD study and highlighted the main concerns that reflect negatively on the development of Health Care System in Kuwait. Most of these concerns and the administrative solutions discussed can be partially or fully resolved, through the development and introduction of the main stages of a NDP. The beneficiaries will be the KMOH and participants (Kuwaiti Government, Kuwait University, Pharmaceutical Association, Medical Association, researchers and private sector) and of course the population of Kuwait.

## Chapter 7.0: Recommendations

During the Research Study, a number of areas of the Public and Private Pharmaceutical Sector have been investigated and explored through collection of the information on the structures and from personal visits to the facilities and interviews and discussions with health professionals who are working in all disciplines and areas of the health services. From this work a number of recommendations can be made and these areas are discussed in more detail below.

The overall conclusion from these studies is that there are a number of issues in the Health Care System in Kuwait, which could benefit from closer examination and decisions taken on whether changes are needed in the future

However one area of legislation which has been strongly supported throughout these PhD studies is that the introduction of a National Drug Policy (NPD) which it is suggested should be a priority to support the efficient development and working of the Pharmaceutical Sector in Kuwait.

In Chapter 5, the basis of the Pharmaceutical Administrations in the Public and Private Sector are described. This Chapter also discusses some of the Ministerial /Ministry of Health decisions; Decrees; and the function of the Health Administrations and the interaction between the Administrations.

Following on from this information, at the beginning of the PhD study, the structured interviews which were undertaken during visits to the public and private health facilities in Kuwait provided the responses of 121 health professionals to the

current position and their views across many levels of the Pharmaceutical Sector (Chapter 4).

In Chapter 7 is an in depth review carried out during the study by the author of this work where in addition to the Interview data generated and analysed in Chapter 5 a number of informal visits were carried out to the facilities of the Pharmaceutical Sector to include the Central Medical Stores, the primary receipt of Pharmaceutical Products at the Airport and the Seaport, the MOH Laboratories, discussions at Kuwait University on Pharmacy/ Health Education programmes, Pharmaceutical Administration, Pharmaceutical Association, Dasman Diabetic Institute, Islamic Herbal Medicine Centre, Drug Control Registration Departments, ten Public Hospitals, two Public Health Clinics, ten Private Pharmaceutical Companies, Private Hospital and the Medicines Inspectorate Offices.

By combining the interview data, discussions at ministerial level, observations during visits and on operational visits, to Laboratories, CMS, warehouses, major receipt areas for medicines and medical devices, it is possible to provide recommendations which could be considered to assist in resolving some of the issues highlighted during this study of the Kuwaiti Health Care System.

Based on the study results two main sets of recommendations (mentioned below) can be proposed:

- Main recommendations, revolving around the introduction of a NDP which can be utilized as a primary source of adjustment in reforming the Health Care System.

- The second set of ‘recommendations’ for the Health Care System can be taken from the results of the qualitative and quantitative data analysis that have been presented in the previous chapters to include:

## 7.1 Main Recommendations

The main 'recommendations' is to address the development of a National Drug Policy. However this is not simply a matter of following a suggestion of the different steps associated with a NDP, as described by the WHO (WHO, 2001), as the structure and development varies from country to country and are dependent on the country's priorities and economy (as discussed in detail in following Chapter 8). Nevertheless there are some main structural points which are considered from this work to be very important in creating the basis for an introduction of a NDP (as discussed in chapter 6):

1. To form a cross-party forum on the introduction of a NPD, which, is aimed at increasing the level of policy discussion and engagement needed to make members of the public aware of the probability of the introduction of a NPD.

This recommendation is based on the fact that the nature of drug policy issues (as discussed in chapter 7): inhibits the assessment of possible changes in the policy. For this reason, it is necessary to produce a discussion space and agreement on the most important aspects of the drug policy as well as possible actions resulting in the enhancement of the existing NDP.

2. There should be clear responsibility for the implementation of the NDP and it should lie with the MOH and not directly with the Government.

In stating this, the author is taking into consideration past examples of introducing a NDP in developing countries, where Government involvement may have been restrictive for reasonably rapid, successful development of their NDP (Normad & Weber, 1998). For this reason it is recommended to shift the responsibilities to the MOH, which could result in formation of new perspectives and forms of leadership, from within the MOH.

3. Once in place the Government should appoint an external body of health professionals, government officials and academics to periodically review the developed NDP policy and determine which sections are working efficiently and which sections need improvement
4. The adopted drug strategies (such as Essential Drug List and Drug Procurement Policy) must presume a commitment to their execution from the initial stages of the policy development.

An NDP should incorporate an aspect of evaluation and learning, which will make it more effective and ensure that they can deliver the claims that will be made when it is proposed and introduced. By ensuring this is part of the Policy, it should result in the ability to address any failed aspects of the policy. Thus, if a particular aspect is not working there should be an opportunity to re-evaluate that aspect.

5. An independent organization from within MOH should be appointed to coordinate and supervise development and implementation of the drug policy.

   The organization should be chosen by the Government to coordinate research in the area as well as carry out regular assessments and monitoring of the implemented policy. It is expected that the organization will be partly financed by the money provided by the Kuwaiti Government to the KMOH.

### 7.2 Recommendations for the health care situation in the State of Kuwait

The Health Care System in Kuwait has many areas to commend it and the support given by the Government is done very well. However, like any major system in operation, its function should be monitored regularly for the good of the public and private sector stakeholders and to ensure that it is financially efficient.

The Health Care System in Kuwait has served the people well, but there are some issues that impede its future development; further to this it suggested that one

major solution would be for the KMOH to consider bringing together all aspects of health delivery under the structure of a NDP. By doing this it is likely it would improve the success factors and solve many of the issues by:

1. Developing the present guidelines for the Legislations and Regulations that relate to medicines.

2. Developing guidelines to ensure that all manufactured or imported medicines in the State of Kuwait are of high quality, safety and efficacy and that they are registered under the Kuwaiti Drug and Food Control Administration and are suitable for human use.

3. Proposing an electronic system linking all the administrative sections of the Ministry of Health, which could lead to improved and increased collaboration within the Ministry of Health framework.

4. Supporting health investment in the State of Kuwait by providing information and distribution about the official legislation, regulations and data concerning the health services to all stakeholders.

5. Suggesting the basis to strengthen the Legislation and Regulations of the health care system, which will better protect the patients.

6. Establishing an Essential Drug List that will promote increased rational use of medicines and ensure that the procured drugs meet the needs of the health care system.

7. Improving the procurement system and supply management.

8. Encouraging personnel development and training and developing increased professionalism and efficiency of the workforce.

9. Establishing quality assurance to ensure control, monitoring and evaluation of work in the public sector.

10. Establishing a pharmacovigilance centre in the country (These points have been discussed in details in Chapter 6).

In order to handle, regulate and organize all of these areas, it has been indicated there is need to establish a NDP in Kuwait that will act as a guide in developing and improving the Health Care System and increase the level of quality and efficiency in health services.

# Chapter 8.0: Proposal for Introduction of the Kuwaiti NDP

Based upon the recommendations presented in the previous Chapter and the work of this study, it can be suggested that development of the Health Care System and access to problem solving of issues in the health sector in Kuwait are linked to the lack of a NDP and all the work of this PhD is based upon proposing how this could be developed and carried out. However before introducing a NDP, there should be an information document which can explain the basis of a NDP and it would then be the responsibility of the KMOH through the NDP group to educate both senior and junior health professionals in order for them to accommodate and understand the importance of establishing a NDP for developing the health sector. This could be carried out by providing a range of initiatives, such as an information leaflet/booklet, short seminars, and/or a conference related to the NDP.

Secondly, the KMOH could create a future action plan to introduce a basis for this project by studying key points such as:

1. How to start working on the establishment of a NDP in the State of Kuwait.

2. The best procedure to regulate and control the work of this national programme, giving an outline of a time period for development of the NDP and setting up its structure.

3. The factors affecting the establishment of the NDP.

4. Steps and stages of NDP establishment.

5. The importance of NDP indicators.

6. Implementation of NDP indicators.

7. The monitoring results during the proposal.

8. NDP implementation.

9. Assessment and monitoring of the NDP.

## 8.1 Establishment of a National Drug Policy in the State of Kuwait

The development of a NDP can be a highly complex process that would normally involve a combination of policy developments and implementation. In addition there should be a monitoring process for the Policy at a suitable time point after it is introduced and then at regular time intervals in the future.

a) In the first steps of the development process it would be helpful to have a National Drug Policy draft.
b) With the second stage the developed activities and strategies, depend on the main objectives of the policy.
c) The final stage would involve the implementation of monitoring activities and any adjustments of the developed NDP from the initial format which was introduced at the outset.

It is proposed that to obtain a successful NDP, there is a need for careful planning combined with an active involvement of all parties. Additionally, it is suggested that as the NDP is in a dynamic state and therefore it should monitored on regular occasions. In introducing and maintaining full operation of a NDP, it does require considerable involvement and checking, however despite many difficulties in the development/operation, over 100 developing countries had a working NDP by the end of 1990s (WHO, 2005).

As a result it is important that the health staff of the KMOH is made aware of the concepts related to the establishment process through awareness of the important combination of procedures which make up this process – **development, implementation and monitoring**. Therefore effective planning is paramount during the first part of the NDP establishment. It is clear from other countries reporting that without this; recently developed NDP's have suffered from very low effectiveness (Babor.et al., 2009).

However to produce a successful outcome of the process, it is also dependant on the implementation actions and activities and therefore the KMOH must also consider carefully these aspects.

Thus at the planning stage the Kuwait KMOH should produce a range of plans and possible alternatives:

a) Initially a strategic plan should be developed that describes the main aspects of the Kuwaiti NDP and the various stages of the policy development, as well as the actions which should be taken to attract as many financial resources as possible from the government.
b) A master or implementation plan should be produced; in order to help the KMOH set a timetable to complete this process. Such a plan would normally cover a period of three to five years and would describe the main activities of the master plan. The master plan should clearly describe the actions that should be taken and the people responsible for the successful outcome of these possible actions. Additionally, this type of plan would estimate a time frame for the policy development and implementation, as well as proposing a rough outline budget. If it was the case that resources are not available and there is no external input, the KMOH would have to consider setting out a range of priorities and goals which they would expect could be accomplishable with the available financial resources. The discussion around the available finance shows that there will be importance in convincing the Kuwaiti Government to support the project if the KMOH are to achieve the desired results.

[ Note: It is also possible to break down the master plan into several annual plans for implementation in various departments or organizations (Babor et al., 2009)].

c) Interaction with external organizations is also of paramount importance to the establishment of the Kuwaiti NDP, such as the WHO, Executive Office of the Council of Health Ministers of the Gulf Cooperation Council, the MOH of

developing countries and other health organizations. This aspect of the policy development presumes that during both the development and implementation stages, negotiations, dialogue and consultations must be carried out between all the stakeholders and interested groups. Thus, interested groups which are expected to participate in the policy development and implementation process are likely to include consumer groups, professional associations, NGOs (Non-governmental organizations), academia, drug sellers, international and local pharmaceutical companies, nurses, pharmacists, doctors and the Kuwaiti Ministries. In this way there would be a strong framework of interested groups in the State of Kuwait. It is also considered very important to consider all the distinct and provincial administrative and medical personnel, and additionally making the necessary effort to take into consideration the place of herbal and traditional medicines and the associated practitioners. In addition to the parties described above, it is considered very important to involve the Kuwait Government drug regulatory agencies/ groups in making contributions in the Health Care System and also representatives of health insurance companies. It is expected that the involvement of the media as well as the support of international organizations will add considerably to the success of the NDP.

It is expected that the above-mentioned committee who would cover the development of the NDP in Kuwait would meet regularly to review and discuss policy implementation with the parties described above in a forum addressing NDP issues (Brienen et al, 2015).

However disagreements are expected within the involved stakeholders. For instance, it may be suggested that commercial interests of the drug producers may be threatened, or doctors may suggest that they could lose their clinical freedoms and some senior staff may be concerned that the reregulation of legislations and regulations or guidelines could reduce their responsibilities and powers.

It is clear that all parties thriving on the existing situation will feel themselves in danger from the forthcoming changes, so the KMOH and those in charge in this project will need to be careful that there is not major disruption caused by those who fear that they will be affected by the development of the Health Care System in Kuwait. Thus the development and implementation of a process that is able to sustain the broad consensus is highly desirable in the policy implementation.

In general, it can be concluded that with the increase in the needs in introducing with time a pharmaceutical industry and elevation in the number of sectors that require improvement, it is expected that more parties will be involved in the decision-making process (Reich, 1994).

Finally, the political dynamics in the views of government present another essential aspect of a successful establishment of the NDP. Formation and the subsequent implementation of the produced NDP both present highly important political processes. This observation is associated with the fact that in the majority of cases the employed policy is aimed at achieving equity of health care to the population through the increase in the efficiency of the pharmaceutical sector, as well as being responsive to existing health requirements and being cost-effective. The described response may be associated with redistribution of power and priorities, resulting in an elevated level of competition among the present interested organizations affected by the reforms, which will be required.

Considering the diversity of the interests involved, as well as the economic importance of the NDP, there may be substantial opposition to the suggested implementations, similar to that experienced in the Philippines and Bangladesh (Lee et al., 1994). Consequently, it is of major importance to identify the main political allies and if possible to sustain their support during the Development Process. Additionally, strategies to confront political opponents should be considered and if possible to put in place approaches which would allow the capability to work with them. Both priorities and decisions which relate to the stakeholders' interests should be considered and balanced on the basis of possible

expected gains and losses. Considerable political leadership combined with sustained development are of particular importance when considering the development and implementation of a successful NDP (Lee et al., 1994).

### 8.2 Setting up the structure of the Kuwaiti NDP

Before thinking about the proposal for introduction of the Kuwaiti NDP and setting up the structure of the policy, it is reported in many research projects and publications that in order to obtain the best outcomes, the project should follow a number of logical steps, with each step subject to critical analysis and assessment. These would include researching the definition, goal, objectives, structure, formulation, process of the NDP, including the WHO recommendations and the successful examples of a NDP in developing countries (WHO, 2001); it also includes finding suitable overall references on development and introduction through sources in the library and on the Internet.

This and the importance of a NDP for the State of Kuwait was discussed with the supervisor(s) – including the External Supervisor Dr Omar, the Assistant Under Secretary for Drug and Medical Supplies of KMOH. From these discussions it was proposed that the development of a NDP would lend support to the possibility of updating and reregulating of legislation and regulations of the KMOH, and the Kuwaiti NDP would act as a guideline for health professionals and help the KMOH to set future plans for the Health Care System in Kuwait. This is especially important as currently this is lacking in Kuwait, and for that reason the chosen topic was the establishment of a NDP in the State of Kuwait.

Through discussions with Dr Omar during the course of this study about the mechanism of action, how to manage and follow-up this project on establishing a

NDP, and around the team that would engage and help to work towards establishing and development a NDP, the creation of a Steering Committee and Internal Department in charge of establishing a NDP was proposed, both of which would be affiliated to KMOH.

Many countries have introduced similar NDPs to the one here proposed in recent decades (Laing, 1991; Ministry of Health, 1994, 2000), and a wealth of information from the WHO and other sources suggests that planning and communication are central to reaching the correct agreements for a NDP (Ratanawijitrasin et al., 2001). In this respect, the researcher suggested to having a number of committees and sub-committees to deal with different aspects of the process (mentioned later).

In the majority of cases of recently established NDPs, various committees composed of public and private sector health workers and legal experts have been established to set-up the systems (Chowdhury et al., 2006). This is true across the world, and established NDPs are continually monitored for best practice by different committees.

An example of NDP creation by committee is provided by Namibia, where the permanent secretary of the MOH established the National Drug Policy committee in 1995 (Ministry of Health and Social Services, 1998). Similarly, in neighbouring South Africa, the National Drug Policy Committee was established in 1994 to set-up their NDP (Laing, 1991). In all cases, the overarching drug policy committee was reported to by several smaller committees focusing on specific issues, such as the essential drugs list or drug pricing. In addition, the laws of Civil services Commission (responsible for all ministries and governmental agencies in Kuwait) obliges the governmental ministries and agencies in the case of on the establishment of any department, administration and organization to be through

working in committees, in order to discuss all views and arguments and ensure achievement to the appropriate results (KMOH, 2000).

The Steering Committee could consist of five members; all of them would be senior staff and the Head of the steering committee would be expected to be Dr Omar. The other members are expected to be:

1. Director of Drug Control Administration.

2. Director of CMS Administration.

3. Director of Drug Inspection Administration.

4. Director of Pharmaceutical Services Administration.

Reporting to this committee would be three sub-committees, which could be the primary means of providing all the necessary information and the required data for the steering committee (See Figure 8.1).

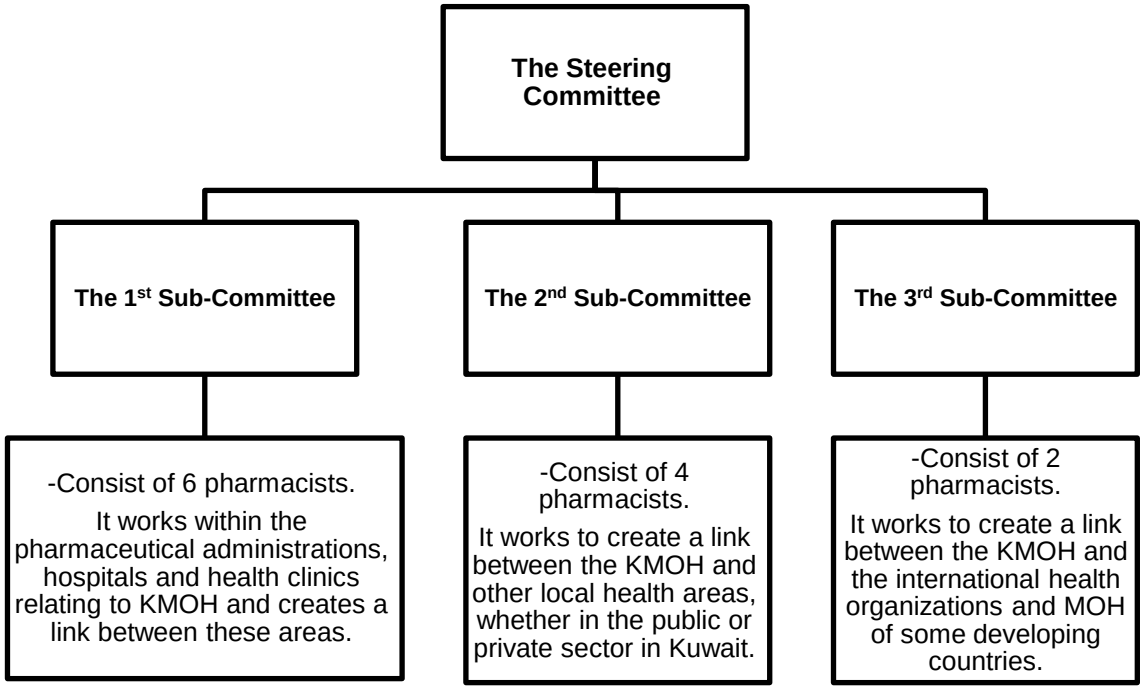


**Figure 8.1. The Steering committee and the three sub-committees of KMOH**

a) The first sub-committee (as indicated in the diagram above) would work within the pharmaceutical administrations, hospitals and health clinics related to the KMOH and create a link between these areas. It is likely to consist of six pharmacists; four of them would work in each of the different MOH pharmaceutical administrations (there are four pharmaceutical administrations in Kuwait), one pharmacist would work in a hospital and one pharmacist would work in a health clinic.

The duty of the first sub-committee would be to talk with and interview their colleagues working in the public pharmaceutical administrations, hospitals and

health clinics in much greater depth to the initial interviews carried out in this study, to:

- Collect more detailed data from administrations, hospitals and health clinics where they work.
- To examine for areas of concern and find any issues relating to the work status of those working in these areas, and relate these to the NDP
- Analyse and suggest solutions to these issues.
- Discuss solutions to try to resolve any problem areas found and relate these to the structures within the NDP, by suggesting development strategies and how these strategies can be incorporated in future planning associated with the NDP. By developing and therefore improving the work in these health areas.
- To bring forward and discuss ideas, advice and recommendations from other health staff to ensure that the setting out of the requirements in the NDP will be suitable specifically for the Kuwaiti Health Care System and the pharmaceutical field.

b) The second sub-committee could consist of four pharmacists working with a remit to create greater links between the KMOH and other health-related organizations in Kuwait. One of their major responsibilities would be to visit all the local organizations, whether in the public or private sector. These include Kuwait University, Medical Associations, Pharmaceutical Associations, Military Hospitals, Dasman Diabetes Institute, the private health care sector (hospitals and health clinics, pharmaceutical companies, pharmacies, drug industries and drug distributors) and other local health organizations. The aim of this committee would be to examine the link between these institutions, the Health System and the NDP and also identify any further concerns, difficulties, possible problems, requested requirements, needs, possible barriers and their potential solutions, and to discuss these within the wider requirements of the Health System and the NDP. It could also discuss the value of their scientific and practical expertise to ensure that this NDP project has a structural framework which includes the interests of all the

health professionals and covers the main points and fields of the health care system in Kuwait

c) The third sub-committee could consist of two health staff and could work towards creating a link between the KMOH and the international health agencies to discuss medicines policy developments and to gain advice on the introduction of a NDP (WHO, Executive Office of the Council of Health Ministers of the Gulf Cooperation Council, Uppsala Monitoring Centre (Sweden) and other international health organizations). Of importance would be the setting up of dialogue and possible links with the MOH of other developing countries, especially those which have had successful experiences in developing a NDP. This committee could after establishing its working knowledge and remit have a meeting(s) with the WHO regarding Kuwait's proposals for a NDP, with specific reference to the general guideline proposed by the WHO in 2003.

In these contacts it is also likely to be important that Kuwait's links with other developing countries, who have introduced a NDP like Oman, Jordan, Nigeria, and Ghana by using official correspondence through the KMOH, emails and official visits to these countries which are likely to be particularly beneficial. The reason for contacting them would be to gain advice on their experiences, to study their successful and not so successful experiences in establishing and developing their NDP. This interaction could go further, by opening dialogue with some of these countries and taking advantage of their successful operations and asking them if they would be willing to provide helpful support to the KMOH in completing the NDP project. However it is important to note that although all possible help and support will be appreciated, the members of this committee should always take into account the specificity of Kuwait's needs and the differences of the factors, nature of work and the needs of each country.

An essential section of the NDP management team will be The Working Party or Committee for the development in implementation of the NDP, who should carry out:

1. Developing the work of the Sub-committees and coordination between them and the NDP Group and the Development/Steering Committee.

2. Arranging the Training and rehabilitation of the chosen staff to work in this field, especially those working in the sub-committees, explaining the importance of a NDP and the benefits that can be gained from it. The department will also inform them about the work plan of this project and how to implement it professionally, providing for all requirements and supporting the teamwork to ensure a quality performance.

3. Follow the work of each sub-committee separately and map the work of each.

4. Evaluating the work of each sub-committee and submitting reports to the Steering Committee and informing it of the progress of the NDP development.

5. Ensuring completion of the NDP by the pre-established time and ensuring the efficiency of the work.

Throughout the process of development the Working should report to the Steering Committee on a regular basis, and the Chair of the Steering Committee should attend the Steering Group Meetings. By having in place a clear structure and an overall independent monitoring committee it is likely to ensure the development and introduction will be successful. With agreed choice of decisions, there should be insight into possible errors before they occur and that no important aspects are neglected

e) The Coordination and Monitoring Department for the NDP. One of the most important operations during and after a NDP is introduced is to continuously monitor its development and operation and it has been proposed to establish an

Internal Department (The Coordination and Monitoring Department for the NDP) to be responsible for monitoring the development of the first draft of the policy. This Department, should be introduced as the process of creation of the NDP which could take considerable time and the Department could through its monitoring induce a certain degree of urgency and insistence of direction when/if the development of the NDP slows down and the time period is excessive. An extended time period could arise due to the complexity of the government work cycle and the presence of established routines. Therefore in order to save time and not to delay this important national project it is proposed to establish the Internal Monitoring Department to keep the process moving.

The main functions of this Department would be that they were responsible for:

- Selecting the appropriate health professional staff for the Sub-Committees and train/supervise them in the introduction of the importance, of the aims and goals of a NDP for Kuwait.
- Supervising their work and making sure they take responsibility for the required actions and incorporate these actions, methods, processes and steps into the future action plan.
- Providing support for the selected staff in terms of any training needs before they start action on this national project.
- Setting up the draft structure of the Kuwait NDP and establishment process through awareness of the important combination of procedures which make up this process – including development, implementation and monitoring.
- Ensuring that all the collected and analysed data by the working group (Sub-Committees) is accurate, appropriate and effective during the process of development and implementation, in addition to ensure access of accurate structures, policy development outcome and results are available for discussion to the Steering Committee before final decisions are made.

It is proposed that in the future, after completing the implementation of the NDP, the KMOH could establish a Drug Administration Unit for the established NDP, which would be responsible for:

1. Continuous development of the NDP.

2. Ensuring the continuous updating of the NDP.

3. Regular monitoring and evaluation of the NDP.

The health professionals working in this administration should be highly skilled in managing, improving and developing proposals and legislation which they can transfer to the development and functions of the NDP, which should reflect positively on the Health Care System in Kuwait.

### 8.2.1 Examples of NDP implementation in Developing Countries

As has been mentioned earlier in the Thesis, the development of a NDP in different countries of the world has continued for many years and although the majority of countries have a working NDP, there are still countries who have to consider its introduction. However in the last 15yr a number of Developing Countries have moved forward with the successful implementation of a NDP and as indicated above these include Oman, Jordan and Nigeria, who generally have some similarity to Kuwait.

However of these, Oman as a developing country has many similarities to Kuwait in terms of population size, proportion and types of common diseases, health services and health care system, and is likely to have come across many of the areas which Kuwait will have to address. It was the forerunner in the Gulf States in the establishment of a NDP, in deciding to improve its Health Care System and to resolve difficulties in its health system through the establishment of this Policy. It was understood from published text (Omani MOH, 2000) that the NDP in Oman has provided a solution for many difficulties and structural issues, and helped organise and structure the work of the MOH and its health system. Oman started

working on establishing its NDP and the organization of the work required over a period of five years, from 1996 to 2000. It was finally introduced and proposed on the 4th of July 2000 (Omani MOH, 2000).

The Omani MOH wanted, through the establishment of a NDP, to achieve key objectives that included:

● Developing the legislation and regulations and following the development of up-to-date

drug registration, licensing, prescribing and dispensing systems;

● To strengthen the rules concerned with drug inspections in the public and private sector;

● Control of imported and exported drugs;

● Ensuring that all the local drug industries in Oman met the GMP conditions and a GPP exists in the pharmacies;

● To improve supply management and drug procurement,

● To develop the human resources (Omani MOH, 2000).

The MOH of Oman has therefore gained expertise in these areas and in developing a working NDP and it would be beneficial if Kuwait can link with Oman and take some advantage from these experiences to help the KMOH to avoid some of the difficulties it may have had in developing their NDP. This is likely to be beneficial in being aware of difficulties they found which may be appropriate in the Kuwait NDP. In addition advice from Oman and other countries could assist in advising on the methods needed to solve some of the organisational and introductory difficulties and ensure the best results are achieved. For this, it therefore may be possible for the KMOH to make arrangements with the Omani MOH for assistance, and be possible to discuss the possibility of sending a work

team to learn about the steps, plans and the methods used by Omani MOH, in order to take advantage of them.

It is also possible to suggest that a similar interaction may be entered into with Jordan. The National Drug Policy in Jordan was formed as the result of cooperation between the Jordanian Ministry of Health and PHRplus (Partners for Health Reformplus) and was introduced in 2002. The premise which was suggested at the time of development was that the formed NDP would act as a framework for subsequent employment in both private and public sectors of the health economy in Jordan. The primary goals of Jordan's NDP were to provide safe, high-quality and effective medical devices to the population of the country as well as to ensure the regular availability of the most important medicines and medical consumables. It was proposed that the development of the pharmaceutical sector would be established as one of the top priorities of the Jordanian reforms. In addition to the actions of Jordanian MOH and PHRplus, they brought in an additional agency, the USAID (US Agency for International Development) to provide an oversight of the developments within the country. The policy was therefore developed as the result of cooperation between the different organizations and Jordanian Hospitals and the Health Ministry (Al-Halawani & Qawwas, 2006).

The specific purpose of the PHRplus involvement was to help the Jordanian Government produce within the National Drug Policy, a National Formulary and a Rational Drug List which would lead to better rational distribution and management of pharmaceuticals, as well as the reduction of expenses in both public sectors and households for pharmaceutical products. In detail the PHRplus were involved in:

1. Promoting and periodically updating the JRDL (Jordan Rational Drug List).
2. Promoting and periodically updating the National Drug Formulary of Jordan.
3. Facilitating the developing and adopting the National Drug Formulary and Rational Drug List by the Jordanian Government.

These activities required the:

a) Promotion of the organizational reforms: Formation of the National Advisory Board, the National Drug Policy Unit and National Technical Committees.

b) Promotion of the mechanisms aimed at rational selection and use of the most important medicines (Hashemite Kingdom of Jordan, 2002).

Based on the information described above and on the discussion of analysed interview data and the collected data from the KMOH (In Chapter 6), it is indicated that a large part of the goals of implementation of a NDP in Kuwait are close and similar to the goals of Jordan's NDP, these include;

- Ensuring the access of safe, high quality and efficacious drugs to the population.
- Ensuring availability and affordability of appropriate needs of drugs in the country.
- Providing an Essential Drug List.
- Developing the process of drug supply management and distribution.

It is however suggested that it is necessary to benefit from the Jordanian experience in the area of establishment a NDP, where it could support the staff of KMOH in this national action plan.

Nigeria is also reported to have introduced and implemented a successful NDP in a developing country. Like Jordan, the NDP in Nigeria was produced and implemented as the result of collaboration with the WHO. The strategies employed in the implementation of the NDP focused on the effective management of the available resources at that time, proposing appropriate quantification of countries medicines requirements and addressing the problem of rational selection of drugs.

Their main requirement in the structuring of the NDP was to establish an effective Drug Registration Department and organize registration of all medicinal products and ensure adequate drug legislation. In addition as Nigeria had an active manufacturing base the NDP attempted to promote manufacturing of local medicines and to try to ensure the quality of drugs was consistently high at all levels. However in practice this aspect was not as robust as it could be and the quality of some of the manufactured products was below the level normally

expected. But the strategies associated with addressing rational drug use and proper accountability for the consumers and health workers, was to a certain extent successful (Federal Ministry of Health, 2003). In establishing a NDP the Nigerian MOH were very aware of the insistence that proper selection of drugs is of major importance to produce a successful operational NDP.

Thus, the Nigerian Ministry of Health established an Essential Drugs List where the medicines selection was generally based around clinical effectiveness and rational selection to satisfy the requirements of the majority of the population. The Drugs List is regularly revised and used to inform the annual procurement selection of drugs by the Ministry in Nigeria. The Essential Drugs List is reasonably regularly updated and made available to health institutions, local governments and health professionals. The drugs included in the list are considered safe because they are chosen based upon international standards and receive a registration number from the Nigerian National Regulatory Organizations (Federal Ministry of Health, 2003).

It is reported that when assembling the Essential List of approved drugs, every effort is taken to avoid formulations represented by more than one active compound. In cases where a range of therapeutically equivalent drugs was assessed, preference is given to the formulation manifesting the lowest price but it still has to be supported by significant clinical data and scientific research. This list formed a major part of their NDP policy and is periodically updated at roughly 4 year intervals (Federal Ministry of Health, 2003).

Based on the information presented above (Examples of a NDP implementation in Developing Countries), it can be indicated that the mission of the third sub-committee is very important; where it would work in creating a link with the MOH of these countries to share and collect all the required data, information and recommendations from them, where it would support the steering committee to take the right decisions in implementation a NDP in Kuwait.

### 8.3 Factors affecting the establishment of the NDP

It is clear that an effective policy implementation is a particularly important aspect of the NDP establishment. As indicated above, regardless of the targeted country in every case a Master Plan and an Implementation Plan must be developed. In this respect each policy component should possess a clear plan of action with the corresponding detailed strategy. However it is important to bear in mind that the establishment of the NDP is affected by factors such as financial resources, regional cooperation among countries as well as with the WHO, and regulation/legislation aspects (WHO, 2005).

Considering financial resources, it is of high importance to match the developed NDP establishment strategies with the financial resources available. In the majority of cases, financial resources are allocated from the revenue generated as the result of drug registrations and from central governmental funds and taxes. The corresponding responsible agencies should be able to quickly and efficiently process applications from the organizations looking for funding and be able to provide governmental funding on the regular basis. But additionally, specialized mechanisms may need to be set up to eliminate conflicts of interest arising as the result of donations. These situations are possible in cases when donors would like to support activities that are considered of low priority for the establishment of the NDP (Turner, 2012). The Kuwaiti Drug and Food Control Administration is in charge of registration, licensing and releasing of imported drugs through the Drug Release Department in Kuwait International Airport; when the KMOH develop the work in this field it is likely to increase income, especially when the Administrations become more experienced and efficient in ensuring the continued availability of income. But as the Kuwaiti Government is considered the largest financial resource for the KMOH, it is important that there is agreement that it should continue to support and assist in the financing of the NDP because it is unlikely that the present income from registration, licensing and release fees is not enough to

support this new initiative, particularly in the development stage. Thus it is likely that the Government/KMOH will play a very important role in supporting and financing the establishment of the Kuwaiti NDP.

In addition to the allocation of the necessary financial resources, technical cooperation with other agencies, countries and the WHO also represents factors affecting successful establishment of the NDP. The WHO through its many discussion, symposia and on-line information materials is likely to be able to offer the basis of a forum for information exchange and it also has available with other agencies the support particularly to Developing Countries to promote cooperation via international and national training courses, as well as providing information on research projects which are currently operating within countries. The Centres which are presently supported by the WHO can take an active part in the development of professional networks, promotion of information exchange among countries and research/training of the professionals involved in the development of projects such as a NDP.

In addition with the information technologies and current means of communication it becomes possible to provide a range of opportunities for low-cost but efficient exchange of information, technical cooperation, collaboration and consultations. A typical example is the Medicine WHO website which provides some of the most recent information regarding technical data, and some documents covering the development and implementation of a NDP. In addition to this website, a considerable amount of relevant information is provided by the Management Sciences for Health (MSH) who is working in cooperation with the WHO.

In addition there are a number of international meetings and symposia, such as the Federation of International Pharmacists (FIP), which is every year and is attended by many health regulators and representatives of Ministries of Health, and WHO

representatives where communication at this major symposium and at other symposia, where there is opportunities to meet with organizations responsible for NDP development (WHO, 2015). It is proposed that it would be the responsibility of the 3rd Sub-Committee to become involved with such developments and international meetings and would further instigate contact with international health organizations and agencies to take advice and suggestions from them to support to development and completion of the process of establishing a NDP for Kuwait. This sub-committee is likely therefore to be the focal point between the KMOH and these organizations.

Based on the information presented above, it can be stated that regional cooperation is as important as cooperation with other countries, agencies and the groups associated with the WHO. As stated above, regional cooperation with Oman and Jordan is likely to manifest very good outcomes in the initial stages of development and implementation of the new drug policy. It is hoped that links with individual organizations, institutions and government health departments both internally and with other countries, can be established where there could be access to experience, facilities, skills, expertise and information between them and the KMOH. Expertise exchange could ensure that the pitfalls are explained and only best practice is promoted and carried out, with a view to try to eliminate the possibility of errors and to introduce the principle of effectively using limited resources. It can be stated that cooperation in the Health Areas already exists at many levels from the regional to International cooperation, covering a number of both health policy and economic issues. Examples of regional partnerships include the; Organisation of African Unity (OAU), European Union (EU), Uppsala Monitoring Centre and the Association of South-East Asian Nations (ASEAN).

In some cases the strategies employed and policies can result in mutual interest, and in these cases the sharing of information as well as technical expertise can be highly effective. Additionally, similar drug regulatory standards are expected to be a

possible outcome of effective regulatory and technical cooperation. Harmonization in these areas can result in the formation of international and regional standards across countries as well as more effective use of materials and human resources. However, in addition to the formation of similar drug standards, sovereignty issues and specific differences from country to country must also be taken into consideration. Consequently, during the harmonization process it should be investigated that every country involved does make sure that harmonized areas are relevant to the corresponding national interests (IPC Group, 1999). In the case of Kuwait it is proposed that the KMOH Drug Department (The Coordination and Monitoring Department for the NDP) which is charged with bringing forward the NDP should be allowed to control such technical matters until the completion of the NDP project. At that point it is probable that the KMOH will establish an individual Drug Administration for the NDP which will have competent to continue all work related to a NDP.

### 8.4 Steps and stages of NDP establishment in Kuwait

In the case of the majority of developed countries who have newly established, or have made alterations to their existing NDP, it has normally (or will be) been adjusted once every 10 years. In many cases these changes to a NDP are promoted from highly important changes in the political profile of the country or sudden emergency situations which can create windows of opportunity for starting the establishment of a new NDP or updating an existing Policy.

Whether a country is up-dating a NDP or introducing a new NDP, there are a number of stages which it is suggested they undertake which can lead to developing a NDP or improvement and harmonisation of the present system. In adjusting the majority of a pharmaceutical system NDP, it is important that the MOH makes itself fully aware of the requirements, factors and specificity relating to the country's needs. In some developing countries there are problems with drug

distribution, while other countries may suffer from the lack of an Essential Medicines List or shortcomings in controlling the pharmaceutical market.

In the case of Kuwait the circumstances facing the KMOH are based upon it being a relatively rich country, but one where the Health System, although it has successfully served the country, it is currently being held back by organisational, communication and limited control over its procurement of new medicines. However within a NDP there are expectations that the KMOH will be able to have more control over procurement of medicines and the structures under which the medicines are chosen and dispensed For these reasons, before the establishment and development of a NDP the country should pass through a number of steps and stages to determine the main aims, objectives, needs, and concerns in the Health System. In the next stage of development an action plan can be proposed with possible, solutions added to the action plan, in order to create an integrated and appropriate NDP for future implementation (WHO, 2004).

The main steps and stages of establishing an outline NDP in Kuwait are summarized below:

Stage I: Organization of the Policy process

The KMOH represents the most important national authority responsible for the formulation and implementation of the NDP in Kuwait. The first stage (after deciding that a NDP is required) should be the effective organization of the development process with the identification of the policy structure, main objectives of the policy, formulation, process of the NDP and primary components. In the first stage it is of major importance to establish the main parties who should be involved and to set out an indication of the required financial resources needed as well as possible approaches to securing them. The necessity of consultations with country officials and donors should be considered at this initial stage. It however suggested that it is possible to carry out this stage within the KMOH with the additional support from a group/committee who can be formed with a small number of the required experts (Chatwin, 2011).

Stage II: Examination the current operational procedures within Kuwait in the health care system

An investigation should be completed into providing a thorough understanding and analysis of the most important operating points existing in the pharmaceutical and medical fields in Kuwait. This is necessary in order to form a realistic set of objectives. A range of approaches can then be used to conduct a situational analysis. To carry this through the approach suggests that there would be involvement of a small 'group of experts' with the necessary policy development experience.

It is however suggested that these 'experts' would be based on the Ministry of Health representatives and can be involved from another local or international health agencies, to possess the necessary training in the relevant pharmaceutical background. The experts should perform the functions of advisers, making the corresponding recommendations to the government of the country. The resulting reports are usually collected and analysed by the MOH (by the steering committee) and discussed later with the WHO. The organization is also responsible for making them publicly available (WHO, 2005).

Stage III: Carrying out a detailed analysis of the Health Care System

It may be necessary to carry out a detailed analysis of the organisation and working of the existing Health Care System and the components of the public and private sectors, as they affect the Pharmaceutical Services. This stage can be considered highly important for revealing whether there are organisational requirements, to establish appropriate strategies, to deal with the findings and to develop the first outline for the NDP. In addition it could deal with any, formation of priorities and provide a baseline for the possible evaluation and monitoring of the systems (Executive Office of the President of the United States, 2015). In order to fully understand the topic and the results from the initial period of study and searches, further detailed research should be carried out to look more closely at the causes of any difficulties, organisational and operating points that are revealed.

To more closely examine their basis and how these can be tackled within the stages of introduction and implementation of the NPD. In this respect from the information above which suggested the introduction of sub-committees in the development phases for the NDP they would look at aspects of the development of knowledge for the NDP, the duty of the three sub-committees in KMOH would be to cover all these functions by interviewing health professionals, researching if there are needs and issues and providing data for further discussion in the appropriate Sub-Committee discussions. Then to propose both the points associated with the findings and possible solutions which can be taken forward by the Working Party Head to the Steering Committee.

Stage IV: Form objectives and goals for the future NDP

This stage proposes that there is a need to define the main issues, to set goals and identify the main priorities resulting from the previous stages finding. For instance, in cases where one of the problems indicated may result from the lack of an Essential Medicines programme in Kuwait, it may be necessary to increase the assessment of the therapeutic value of the most important drugs as well as improve distribution, affordability and selection. Strategies involving selection and procurement are complex processes due to the fact that there may need to be specific organisational structural changes to selection and procurement of specific drugs which is difficult to carry out rapidly. As a result individual approaches may be required to address each situation. Additionally, it may be necessary to carry out a meeting with participating primary health/policy professionals.

Thus in carrying through the main strategies for handling the choice and procurement of drugs it will be necessary to agree objectives and to discuss them with the interested organizations and individuals. In the early stages a well-structured situational analysis can provide the basis for the decision-making process and justify the choices made.

Once the primary strategies and objectives have been determined, the necessary consultations with all the interested parties would be carried out. The discussions

and outcomes will require careful consideration and broad consultation, with corresponding acknowledgement of possible conflicts of interest as well as structural constraints, but the outcome from discussions will be required to produce working decisions, objectives and to develop possible strategies which can be carried forward into the draft of a working NDP (WHO, 2005).

Stage V: Produce the initial draft of the NDP

It is necessary to produce the policy draft at the point when the situation existing in the country has been thoroughly analysed and the main goals, approaches and objectives established. The initial draft should include the main objectives of the developed policy. In the majority of cases, the main objectives presume the availability of the most important drugs, safe use of drugs by the total population of the country, and their good quality and rational prescription by health professionals. Additionally, specific objectives must also be described along with the corresponding strategy that should be adopted. Formation of the policy draft can be carried out by a team of experts, employed in the previous stages of the development process. During the draft development stage it is also highly important to consider successful examples from other countries (Fresle & Wolfheim, 1997). The steering committee (consisting of senior staff) is in charge of producing the initial draft of the Kuwaiti NDP after they get the required data from the sub-committees and the internal department for the NDP.

Stage VI: Revision of the initial draft policy

In order to revise and refine the developed NDP it is important to circulate the document, initially within the MOH and subsequently within other Ministries and Departments of the Government and finally, within relevant organizations, private institutions and academia. At this stage it would be expected to receive endorsements from the Government, because the Government is responsible for education, finance and planning operations within the Health Ministry. Circulation

of the document within the institutions and organizations would be expected to lead to remarks and comments being made through representatives of these organizations. Consequently, at the point when the consultation stage is completed, all the received comments must be considered and the policy draft finalized (Normad & Weber, 1998).

Stage VII: To secure Governmental endorsement of the developed NDP

In a range of countries it is possible that the developed document would be sent to the parliament or cabinet of ministers for the necessary endorsement. It is also possible that the document will be employed as the administrative basis for the introduction of changes and plans for the existing regulations and law. In clearing the introduction of a NDP it is likely that a substantial political commitment is required through the Government and the MOH, because agreeing changes to existing procedures and Laws (Decrees) should be well checked as any further major adjustments in the future may be difficult. In a number of countries the developed NDP has been fully accepted by their governments and has led to a series of decrees or statement which are now legal requirements (WHO, 2005).

Based on the information presented above, it is suggestion that the KMOH could follow the process mentioned by presenting an official request (with attachment of the main goals, benefits and advantages of this National Plan) to the Kuwaiti Council of Ministries (Kuwaiti Cabinet) and the Kuwait National Assembly (Kuwaiti Parliament) to get the endorsement for establishment a NDP in Kuwait. But as potential adjustments are commonly needed it is usually recommended that only a range of aspects from the developed Policy are implemented as law and the remaining points considered as recommendations (WHO, 2005).

How will this aspect be handled in Kuwait? During a number of discussions with the Assistant Undersecretary of Drugs and Medical Supply Affairs in the Kuwaiti

MOH (Dr Omar) and the author of this Thesis, it was agreed that he would submit an official request to the Prime Minister of Kuwait to meet with him in the presence of the Minister of Health. Such a meeting would allow Dr Omar to explain the importance of this NDP project and the extent of the benefits that Kuwait may be obtained from it, and to ask him, with the Minister of Health to consider supporting the principle of a NDP and to consider bolstering the KMOH in order to complete the establishment of the NDP. In addition Dr Omar submitted an official request (in 2013) to the Minister of Health and the Undersecretary of MOH, where he suggested a proposal for establishment of a NDP in Kuwait to keep abreast of developments in the health care field.

Stage VIII: Introduction of the developed NDP

In addition to a series of challenging technical tasks, the introduction of a NDP includes a series of communication issues that must be resolved. Thus, it can be stated that to a considerable extent the success of the policy will depend on the understanding among various society sectors and organizations as well as their support of the introduced policy. Consequently, it is highly important in gaining these groups support to establish clearly the probable benefits for the participating organizations. It is also necessary to promote the implemented policy via a well-designed and clear informational campaign. At this stage, endorsement from the public as well as political leaders and experts in the field can be highly advantageous. However this aspect will need to he handled sympathetically as the public are often suspicious of changes (Babor et al., 2009).

In order to reach the necessary target groups, various means of communication and information distribution should be used. In this respect it will be important to use the strength of the media who can play a significant role in the distribution of information and ensure public support and understanding of the intended drug policy. As an example of how this can operate, literature reports are available for a range of countries, where high profile drug policy introductions were organized (Babor et al., 2009). Therefore it is considered essential that one of the KMOH sub-

committees (possibly No 3) takes steps towards publicising that the NDP has/will be establishment in Kuwaiti NDP to the public and associated groups and agencies. Particularly to indicate that the NDP will be a qualitative leap for Kuwait and the KMOH in the reform and development of Health Care System, where there will be considerable advantages in supplying the Pharmaceutical Services to the population of Kuwait.

### 8.5 The importance of NDP indicators

Both evaluation and monitoring are highly important and extremely challenging aspects during the development and implementation of the NDP. Factors which will come under these indicators will be; to consider time restraints, the lack of necessary budget, human resources and ensuring full understanding of the value of monitoring. There is also the expectation that there may be resistance to introduction of close monitoring. However it will be essential to critically and objectively assess the outcome of activities outlined and implemented in the NDP Master Plan. In order to assist in introducing such an important assessment of the developed and implemented NDP the establishment of a Drug Administration for the NDP has been proposed, and it is suggested it should consist of a trained and qualified team who can work to avoid the difficulties above.

After completion of the development of the Kuwaiti NDP, it is proposed that the Administration should follow the implementation, evaluation and monitoring of the NDP, because to not to pursue these aspects is likely to reduce the benefits and privileges of a NDP in Kuwait.

Overall monitoring can be described as a continuous review, the purpose of which is to present a clear picture of the activities carried out and establish whether the objectives initially set were/are being met. Monitoring can take various forms from physical monitoring to structural procedures. In this latter respect it is possible to carry out monitoring operations with the aid of a series of structured methods, such

as a combination of ‘sentinel reporting’ and ‘periodic supervisory visits’. In turn, evaluation represents a form of progress analysis that presumes regular assessment of the progress made towards the previously established goals and objectives.

At the initial stages of the programme evaluation, methods can be based on the monitoring carried out and employed to establish the main needs of the country in the area of drug distribution. At the next stage, the purpose of a mid-term evaluation would be to provide the necessary information showing whether the implemented programme works. The final evaluation would provide a total assessment of the progress made and the achievements of the programme, which are employed to draw the corresponding lessons for the future programmes. A monitoring and evaluation system can be a sophisticated management tool that makes it possible to carry out a continuous process of assessment and make from the information generated the required decisions. The system also provides the required evidence of progress, which results in the support of the introduced policy in the dialogue with policy makers and interested organizations (Brudon-Jakobowicz et al., 1999). It is proposed however that the KMOH and senior staff of the Steering Committee should bear in mind the importance of these indicators to ensure the continued success the NDP project.

Taking into consideration the information outlined above, it is clear that the choice of NDP indicators is highly important for the successful implementation and continued success of the drug policy. Thus, in order to establish if the expected progress is attained, it can be very helpful to define performance standards and produce realistic targets. In this case NDP indicators can be introduced to compare sets of results, detect changes and establish whether the expected targets were met. The indicators employed are expected to be valid, reliable, measurable, useful and clear.

Some of the most important NDP indicators were developed and subsequently refined by the WHO (Trap et al., 2006). Thus, the main indicators currently employed by a number of countries often consist of; outcome indicators, process indicators, structural indicators and background indicators. These indicators can be employed individually or in a combination, to meet the needs and requirements of a particular country. It is proposed that the administrative committees for the NDP in Kuwait can establish a standard complex of core indicators to include both sentinel reporting and routine use., as discussed in the WHO documents (Trap et al., 2006). It is important that the indicators chosen are standardized, making the observed trends easy to identify. Additionally, collection of data can be easier, resulting in efficient and regular monitoring.

Core indicators which can be employed to cover the following aspects of the NDP:

1. Access to the most important drugs and their supply to the general public. The indicator is employed to address the availability and affordability of Essential Drugs.
2. Efficiency and functions of the organisations regulating drug distribution, handling of the drugs and the work in the laboratories, providing drug quality control. This indicator can be used to address drug quality issues.
3. Description of drugs and the use of Clinical Guidelines and an Essential Drugs List. This indicator can be employed to address patterns of drug use (MSH, 2005).

Both the Sentinel and Routine Reporting are likely to be of major importance as part of the different types of indicators used. A routine system of reporting should also be introduced to give some consistency in the drug management system, and will aid the provision of information necessary to monitor the development and implementation of the drug policy. However, in the actual data collection environment the main bulk of the information may not be obtained by systematic methods and in these cases a system which is consistent will need to be introduced. In cases when the sentinel system of reporting is employed, it is likely

to be necessary to regularly survey the most important health facilities. Looking at recent examples, the value of this type of data collection, for the corresponding NDP indicators, was employed in Zimbabwe, where over a period of two years it was possible to establish weaknesses and strengths of the most important facilities of the country's Health Care System. As a result of these studies, it was possible to develop a highly effective managing mechanism (Trap et al., 2006).

It is possible that the indicators outlined above, as well as management systems applied in the pharmaceutical sector, can be employed by a range of parties working in the pharmaceutical area. To include managers, policy-implementers and policy-makers who can use the NDP indicators to investigate the problems existing within the country, develop the primary strategies and set priorities. The results obtained can also be employed to improve the existing procedures, aiming for maximum impact.

In addition the results can be employed by both Health Ministries and Governments to synchronize their policies. For instance, if the indicators point out low levels of affordability and availability of the most important drugs, policy makers can conclude that current directions on drug and health financing should be reviewed. This scenario is possible due to the fact that the majority of countries are looking to join the global economy, but with no particular consideration of the implications of the actions carried out on drug pricing, medicines and their cost and quality can be major issues to include consequently on their availability and affordability.

The existence of substandard drugs on the market of a country may result in the need to review the implications of the existing free market, associated with the existence of foreign drugs in quantities that the drug regulatory organizations cannot efficiently control. Both donors and international agencies can employ the results on medicines to establish the priorities in the sectors that require the most support and assess the viability of resource investment in areas where maximum

impact is expected. Additionally, results from NDP indicators can be applied by the professional groups to establish the areas which require information on the existing drug policy and create advocacy campaigns promoting the use of new techniques or drugs (WHO, 2005).

In addition to within-country assessments, NDP indicator results can also be employed in multi-country cooperation programmes. Thus, multi-country investigations implementing standard approaches can be used to establish innovative techniques that can subsequently be employed in other countries. Multi-country evaluations can also be used to promote international collaboration and exchange of information covering drug policy (WHO, 2003). Despite the fact that the organization is able to inspect drug retailers and manufacturers as well as register new drugs, the enforcement abilities of the organization are limited. The most important indicators outlined above are recorded by the WHO for the subsequent international comparison and are employed by the organization to make reports covering the world pharmaceutical industry and drug distribution (WHO, 2003).

Finally it can be suggested that the indicators presented above can be used to carry out periodic assessment of an existing NDP. In this respect it is advised that the implemented NDP is evaluated at least once every four years. In order to accomplish this task, it may be that independent professionals and consultants could be attracted from either international agencies or other countries to work together with the national team of experts. Monitoring and evaluations methods should be listed in the previously described master plan, with the expectation of allocation of the corresponding resources at the planning stage (Chatwin, 2011). From the information given above, the proposal to the KMOH is that they should accommodate the importance of NDP indicators and not neglect this aspect.

## 8.6 Implementation of NDP indicators

As established in the previous sections, in order to assess the performance of the implemented NDP it is necessary to consider the use of outcome, process, structural and background indicators. The indicators presented can be employed individually or in a combination. It is suggested that initially background indicators are applied. The purpose of this type of indicator is to provide data covering the existing demographics, pharmaceutical, health and economic situation of the country in which the developed drug policy is applied. The information can be collected in quantitative form, describing a certain single point in time. In the majority of countries this information is immediately available at the start of the indicator implementation (Buse, 2009). In Kuwait there is no concern about the availability of background indicators because the KMOH would normally provide data for the working committees, whether on ministerial decisions, charts, statistical tables or other information.

Also the private sector is likely to cooperate, to provide the required information and will support this project if they believe that the results will be positive for their work. The Kuwait University (Faculty of Medicine and School of Pharmacy) as well as medical and pharmacy associations would be expected to provide help; as they have indicated their support during the interviews with them during the course of this research, where they showed interest and asked to participate in the work of this project, and especially after they were involved in discussions and explanation of the importance of a NDP, and how it will positively affect the health system in Kuwait.

In addition to background indicators, it is advised that structural indicators should also be used to assess the outcome of the application indicators'. The purpose of this set of indicators would be to produce qualitative data assessing the capability

of the pharmaceutical system and to achieve the objectives of the implemented policy in the country. Structural indicators are aimed at establishing whether the most important mechanisms, systems and structures required by the NDP implementation are fully developed and introduced. Based on the information obtained at the central level, the structural indicators used can provide “yes” or “no” answers. The WHO suggests that structural indicators can be used to assess the presence of the necessary elements, highlighted initially in developing the NDP (WHO, 1999).

Process indicators should be applied after the application of background and structural indicators. Their purpose is to provide quantitative information describing the processes through which the NDP is implemented. Process indicators can describe the magnitude of the activities required to achieve the necessary objectives and the progress that is made over time. Like the structural indicators, monitoring of the main activities is conducted from the perspective of the implemented NDP. Also, as in the previous cases, information obtained at the governmental level or via the use of surveys is used to collect information for the process indicators.

Currently, the process indicators that are documented are used to assess NDP performance, with the final set of indicators aimed at measuring the results achieved and assessing the observed changes in policy associated with the implemented NDP. The WHO has developed 10 outcome indicators and, as in the case of the previous types of indicators, the data can be collected through the use of surveys or official, governmental sources. In particular, the purpose of outcome indicators is to measure the effects of the employed policy on the objectives outlined in the NDP. For instance, possible objectives can include rational selection and use of drugs as well as affordability and availability of the most important pharmaceuticals (WHO, 1999).

Overall the main purpose of the NDP is the improvement of the health of the total population of the country (Smith & Hanson, 2011). To achieve this, the place of the indicators in the implementation of the NDP should be carefully considered for a number of reasons. First of all, the complex nature of the existing health status should be taken into consideration. Additionally, highly complicated causality issues connected with the drug policy should be considered. Finally, highly complex methodological difficulties associated with the selection of health indicators should be resolved. It should also be assumed that the findings obtained as the result of applying the indicators should have an impact on the accessibility and availability of the most important drugs and their quality, and consequently, should improve the health level of the total population of the country. In a range of circumstances managers responsible for the application of indicators may want to apply only certain indicators selected from the ones outlined above. It is suggested however that the number of the applied indicators should only be reduced when the parts of the NDP assessed are relatively simple, but the collected data should be analysed with greater care (Smith & Hanson, 2011).

Considering the application of the indicators, it can be stated that according to the WHO statements and the many publications in the area, the developed indicators should be employed in their current state, with only minor alterations addressing individual circumstances of the country in which they are applied. It should also be ensured that their application results in the formation of a comprehensive assessment of the applied NDP. This effectiveness of the indicator application was supported by recent assessments carried out in 12 countries, where the assessment of the pharmaceutical policies implemented was carried out in a range of socioeconomic contexts. Nevertheless, in any country it is expected that the responsible managers will alter the indicators to correspond to national circumstances (Drummond et al., 2005).

It is possible to apply a range of techniques to alter the NDP indicators. First of all, it is possible that in addition to improvement of the Health Care System, the assessed country may have its own set of objectives, such as implementation of traditional medicine or development of its own pharmaceutical industry. In this case, introduction of supplementary indicators at the country level can be suggested. This example is similar and applies to the health situation in Kuwait, where one of the objectives of this project is the implementation of traditional medicines, because there is only one specialized centre (Islamic Herbal Medicine Centre) for Traditional Medicine in Kuwait. During this PhD Study there was a visit to this centre and the visit showed that the centre may not be at the required level of efficiency – as it appears there are not enough employees, a lack of laboratories, equipment, training courses for the staff, and the existing library is small and lacking in adequate reference books. So they are likely to need to develop this centre and build more centres to improve the traditional medicine field.

In Kuwait there is only one commercial pharmaceutical industry and it is obviously not enough to provide for the needs of the population; for these reasons the implementation of traditional medicines and the development of pharmaceutical industries in Kuwait should be set as an important area for expansion. This type of introduction should be accompanied with careful identification of the main objectives and primary strategies, resulting in the selection of indicators that may afford highly important information regarding the usefulness of the development of this area in the NDP.

Additionally, it is also possible that managers operating at the national level may decide to employ normative standards for the indicators, taking into consideration specific priorities of the country (Jackson, 2012). It is clear that all countries are different, they manifest different socioeconomic development, political structures and consequently, possess individual priorities. Alternatively, the use of provisional standards complementing outcome and process indicators can be suggested.

Nevertheless, the managers responsible for the implementation of these standards should review them carefully, in order to ensure that they meet the goals and targets of the NDP.

In addition to the cases described above, it is also possible that managers at the national level will require more detailed information regarding the most important aspects of the implemented drug policy. In this case the employed indicators should be subdivided. Thus, the indicators referring to prescribers in a general sense can be converted into more specific ones through their adaptation to various types of prescribers. It is very important to consider that the primary objective is to monitor and evaluate progress of the policy implementation and not to carry out all the activities presumed by the indicator.

In addition to the potential alterations outlined above, it should be mentioned that due to substantial differences between countries, some indicators may be more important than others. In this case it is possible to exclude the indicators that are not relevant from the assessment, and based on the WHO assessments, in the majority of cases inapplicable indicators are removed or altered in the context of developing countries (Glied & Smith, 2013).

It is possible to successfully apply the NDP indicators described above only in cases when the assessed country has the necessary infrastructure for monitoring their existing drug policy. In such instances the WHO recommendations could be applied to collect the necessary data, carry out the indicator-based analysis and produce the corresponding reports. In countries with reduced organizational activities, WHO recommendations could be followed initially to establish the basis for an adequate industrialized monitoring system as well as development and introduction of the NDP. The purpose of the recommended monitoring system is the supply of the required information with no need for specialized ad hoc investigations. While introducing the system supporting implementation of NDP indicators, it should be presumed that during the first years some data will be

collected via specific surveys, because of the reduced efficiency of the employed systems. In this type of situation it is advised to develop a method that would presume a balance between logistical simplicity of the model and collection of accurate data. In a range of countries, it is also possible to start applying the indicators with a minimal number of possible activities and expand the process with the development of the monitoring system (Briggs et al., 2006).

The Organizational Department responsible for drug policy implementation, as well as the corresponding indicators assessing the performance of the system, could represent a MOH subdivision, working either in the Planning or Pharmaceutical Department. Even in cases of extremely decentralized health systems, possibly with minimal activity by a MOH, a degree of central capacity for implementation of a developed NDP and monitoring of the corresponding results is highly desirable (Morris et al., 2012).

Once the necessary data collection systems are introduced, the process of using the NDP indicators would normally require the steps outlined below to:

1. Determine the targets in each of the assessed objectives and policy. It is advised that this step should be carried out at the planning and policy formation stages.
2. Establish the required indicators and the data that should be used.
3. Assist in data collection.
4. Analyse and subsequently interpret the data.
5. Propose changes based on the results obtained.

Based on the information above, it can be stated that the outlined institution-based process of using NDP indicators in Kuwait may require involvement of external parties as well as the commitment of the corresponding policy makers. Thus, it will be possible to ensure the effective use of the NDP indicators, which should result

in effective improvement of the existing NDP, once introduced. For this reason it was suggested that the use of the NDP indicators should form an intrinsic part of the national health system (Buse et al., 2012). It is also suggested that it should be possible to choose required and important indicators in Kuwait successfully, as members of the steering committee, its sub-committees and an individual department for NDP should come from all categories of health professionals, and in particular from the most experienced in Kuwait. Among them should be senior and junior staff, and a range of pharmaceutical administrations, hospitals and health clinics. This should mean that all the health areas are covered and that the search process for good practice, structural developments, finding any issues, analysis of results and finding solutions and defining strategies could be through their experience all-encompassing, and thus ensuring that the impact of indicators on the development and implementation of a NDP is highly efficient and effective.

### 8.7 The use of monitoring results

The indicators outlined above can only be considered useful if their results are employed to support the development of Kuwait's NDP or to suggest necessary alterations, once it is in place. It is important to note that data collected should always be analysed fully as recent publications have indicated that in a considerable number of cases the collected data has not been fully analysed, or is analysed but the results are not used to modify or improve the existing policy or practice. For this reason, the WHO and other authors have indicated that the monitoring results should generally always be used to elevate drug policy effectiveness (Guinness, 2011, p. 85).

First of all, the indicators outlined above can be employed to monitor the success of the implementation of various components of the developed NDP. For instance, typical problematic areas can include lack of basic structural components and

adequate functioning of the most important components. Additionally, with the aid of the generated results it is possible to establish the components that require improvement. In cases where the indicators were used during a certain time frame, it could be possible to establish whether the assessed components of the policy declined or improved in performance (Wonderling et al., 2005).

Secondly, the results of the indicators could be employed to establish the current priorities of the pharmaceutical sector as well as to determine the effectiveness of the implemented drug policy approaches. Thus, in cases when one drug policy component provides poor results compared with other components, the allocation of increased financial and human resources and commitment could be considered, and consequently, a reassessment of the priorities of the implemented drug policy components. In a range of cases, alteration of the existing strategy may be suggested. It is possible that this goal can be achieved by introducing the corresponding schemes promoting the use of an Essential Drugs List. Additionally, development of a new pricing policy could be suggested, which should result in the encouragement of private distribution of the most important drugs (Guest et al., 2013).

Thirdly, the results manifested by the indicators can be employed by both international and national companies to compare the performance of various drug policies employed by different countries. Thus, by comparing structural indicators it will be possible to establish relative strengths and weaknesses in the ability of the country to employ the developed NDP, while process indicators could be used to establish the progress in the completion of the drug policy goals. Cross-national modes of comparison can also be used by policy makers at the national level, to learn of new innovative methods applicable in their particular countries (e.g. for the Kuwaiti cabinet and parliament). Additionally, the country data collection carried out by the Essential Drugs Departments could be used to support the development of the corresponding international database describing the formation and use of a

NDP, but because the KMOH does not have this department, it proposed to convey this work to the committees and a temporary department. This type of database could be distributed worldwide to support policy-makers in all participating countries in assessing the performance of the pharmaceutical sector of their country and the developed NDP (Lewis et al., 2008).

Finally, the collected results can be used during negotiations covering changes in drug policies among interested organizations within Kuwait, as well as discussions with international agencies and external donors regarding reforms in the Kuwait health system. The employment of the indicators over a prolonged period of time could be used to manifest the impact of various changes in the macro-economic policy on the pharmaceutical and health care system. The NDP indicators can be employed to collect data that would enable Kuwait policy makers working in the health sector to put forward more coherent and persuasive arguments during their discussions, which should result in the protection of the interests of vulnerable groups within Kuwait and during periods of economic and organisational change (Donaldson & Scally, 2009). The health team working on the establishment of a NDP in Kuwait should be aware of the necessity of using the monitoring results because it is a very important step – all the decisions, recommendations, solutions, planning and strategies will be based on the collected data, and the results of this outcome could determine the success or failure of the work. However all staff at all levels should undertake educational and training courses about the steps of establishment of the NDP, the indicators, development, implementation and monitoring before starting to discuss the NDP for Kuwait.

### 8.8 NDP implementation

Based on the information presented in this Chapter, it can be indicated that the success of NDP implementation is dependent on the evaluation of the country and

its health needs, as well as the formation of effective Master and Work plans covering which could cover a period of around three to five years and address the health priorities of Kuwait. Additionally, appointment of governmental officials responsible for the implementation of the NDP plan may be required (Babor et al., 2009).

Each country has its own set of priorities. For instance, in the case of a country with a well-developed Health Care System and access to a variety of drugs, rational drug usage, control of drug cost is unlikely to be one of the main NDP priorities. It is expected that in this case the NDP employed should be focused on marketing control and actions which in turn will result in control of drug costs with no reduction in their quality. However in developing countries, overall spending on pharmaceuticals/health will generally be low and the private sector will not be able to meet the needs of a considerable proportion of the population. In this case the NDP should be focused on the supply of Essential Drugs. Where a NDP is to be introduced certain priorities should be set out and included in the Master and Work Plans. Development of a NDP presumes the formation of an implementation plan, which should be part of the Master Plan, covering a period of three to five years (Guest et al., 2013).

All these aspects should be studied in general but decision-makers in the KMOH will understand that although these issues may be found in some developing countries it does not mean that the Health Care System in Kuwait is suffering from limitations in all the areas. As was said in the early part of this Chapter, the Pharmaceutical Services in Kuwait have served the country well. For example, in Kuwait there is no issue with drug distribution (more develop is needed), access and affordability of drugs and lack of financial sources. Therefore these aspects should not be included in the master plan, to save time, effort, and financial resources.

In developing the Master Plan it should outline the most important components of the developed NDP, the required actions and the budget necessary for successful NDP implementation. If financial and human resources are insufficient with no external input, a range of the most important activities should be produced that can be carried out with the available resources. Nevertheless, it is also very important to determine the gaps in resources for consideration of future support. One of the purposes of the Master Plan is to facilitate the follow-up and for monitoring. Consequently, it is very important that it is distributed to all the involved parties. To clarify the details the Master Plan should be broken into a series of action/work plans. These plans could cover a period of one year and describe actions carried out by individual organizations. In particular, it is necessary to estimate time frames and required budgets, describe the expected output all of which is likely to be scrutinised during the monitoring indicator process and detail the most important tasks and individuals responsible for success (Normad & Weber, 1998).

The implementation of the plans outlined above should be supervised by the Working Party of the NDP and coordinated by the Steering Committee and KMOH. In many countries this role is performed by a specialized subdivision of the MOH and it has been indicated earlier in the Chapter that the responsibility for implementation should lie with the working party (The Coordination and Monitoring Department for the NDP and Sub-Committees) who would report regularly to the Steering Committee. It performs coordinating functions with its own personnel and budget. In addition to coordinating groups, it is also essential for overseeing the implementation of the policy through national consultative forums. This type of action is vital to create and subsequently to maintain the implemented policy countrywide as well as ensure that the most important stakeholders are well informed and remain involved. Similar types of supervision can be introduced for highly specific components of the policy, such as rational drugs use and quality assurance (WHO, 1999).

The KMOH Steering Committee-Sub-Committees and the Coordination and Monitoring Department for the NDP would have an interest in setting up

conferences specialized in the establishment of a NDP with the participation of the WHO, KMOH health professionals, MOH staff from developing countries, GCC Ministries of Health, international and local agencies, Kuwait University, health associations, local agencies, international drug companies, the private sector and foreign experts in this field. If these conferences are repeated more than once during the period of work of the master plan, they ensure the contribution of experts to this project and the correction of mistakes in the work if found.

In addition to the KMOH, other key parties in the implementation of a NDP in Kuwait are provincial and district health services, CMS and drug regulatory agencies. Successful implementation is also dependent on the actions taken by other agencies involved in education, planning, trade and finance. Finally, taking into consideration the magnitude of possible pharmaceutical issues, it is essential to both obtain and sustain the consensus formed on the primary objectives of the policy.

### 8.9 Assessment and monitoring of the NDP

In the previous sections it was indicated that assessment and monitoring of the NDP is a very important aspect of Health Care System development. The NDP assessment should be determined by the methodology employed to calculate the indicators described above (Carr et al., 2007).

The methodology used in calculations should be based on the following aspects:

1. Organization of the data collection.
2. Data collection procedure.
3. Analysis and reporting of the obtained findings.
4. Survey implementation.
5. Determination of the cost of the most important drugs.

During the assessment and monitoring of the implemented NDP, establishing adequate indicators and sources of data, determination of the approaches to the data collection and analysis of results should be carefully considered, such as careful identification of adequate indicators combined with the quality of the collected information should provide the most significant effect on validity of results and the necessity for proposed changes. In order to make sure that the results assessment obtained accurately represents the performance of the NDP, it is suggested to be necessary to follow the steps outlined above (Carr et al., 2007).

As indicated above, organization of the data collection represents the first step of a successful assessment and monitoring of the NDP. In order to accomplish this task a team of the Steering Committee – Sub-Committees must be formed at central level, working in the national drug authority or the KMOH.

In addition the team of the Steering Committee – Sub-Committees and the Coordination and Monitoring Department for the NDP described above must establish the indicators to be used in the assessment, identify primary sources of data, and determine the techniques employed in the data collection, plan the data collection time frame and estimate the required budget as well as main resources. Estimation of the budget and necessary resources represents one of the most important aspects of the initial stage of NDP assessment. Thus, the appointed team of the Steering Committee – Sub-Committees and the Coordination and Monitoring Department for the NDP could prepare a detailed report addressing the time necessary to collect as well as carry out data processing and analysis operations at both peripheral and central levels. The budget must take into consideration costs of supplies, transportation, and personnel as well as monitoring units (Wilson & Mabhala, 2008).

The following stages of assessment and monitoring of NDP should be focused on the data collection operations. At this stage two highly important aspects must be addressed: development of the data collection methods and their successful implementation.

It is advised that data should be collected through the use of specialized forms, designed, tested and approved by the MOH or another agency such as the WHO. The described forms should subsequently be employed to collect data from interviews and surveys. It is also highly important that the data collection operations are carried out by selected and trained staff. Thus, two groups of collectors can be established (within the Sub-Committees): the purpose of the first group is to perform the surveys while the second collects information based on interviews and records. It is of paramount importance to ensure a high quality of collected data. The data should be valid, reliable and accurate. In order to address this issue both evaluation and supervision operations should be carried out by a specialized monitoring unit, formed by properly selected and trained data collectors (Baggott, 2010).

Calculation of the indicators employed and the analysis of findings should be suitable for presenting one of the most important aspects of the assessment and monitoring of the NDP. It is proposed that the operations to be employed in data analyses should be finalized before the data collection methods are carried out. Using suitable data collection methods will considerably ease the processing aspects.

It is proposed that the processing operations would be carried out by the specialized monitoring unit (The Coordination and Monitoring Department for the NDP) working at the national level, who would receive the results of the surveys, reviews and any interviews. Although it is possible to manually perform the required calculations; the implementation of computer-based techniques can substantially increase the speed of the assessment and accuracy of the findings. In

the data collection stage a check on the authenticity of the data and the processing is required. To these figures a level of quality control should be implemented during the analysis. The checks would include assessment for internal consistency and completeness (Douglas et al., 2009).

I addition to ensure that the results obtained from the Sub-Committees are under quality standards, it should be checked by the separate Monitoring Department or section to validate and ensure that all the results are a valid assessment of the reality of the health status in Kuwait.

It is proposed that the results obtained should be reported and employed in improving the existing health system. A corresponding report can then be presented by the Coordination and Monitoring Department for the NDP [Monitoring Department] to outline the information collected, and to define the main results and the most important conclusions. Subsequently, the report can then be used to form a basis for the majority of new decisions on the development of drug policy. Additionally, along with official reports, information could be presented using printed and on-line articles and presentations. Particularly during the introduction of the NDP it will be important to address specific problems and tailor the information presented to possible solutions and then further specific actions. Thus, it is expected that the resulting actions will take place on three levels: 1) the level of the health facility, 2) the specialists' audience and 3) the Governmental level. At these levels three types of action are expected: a) those which are recognized as the most effective actions and encourage them, b) change are proposed for the aspects that do not work and c) altering of the policy in areas where poor results were recorded (Mckee, 2011).

The implementation of specialized surveys is another highly important aspect of the assessment and monitoring operations. Thus, despite the fact that all the data required for the indicator calculation can be collected using existing systems of monitoring as well as interviews of the government officials and document reviews,

at a central level, the calculation of a range of outcomes and process indicators may require the individual completion of surveys carried out in medicines outlets and health facilities. As it is possible to organize surveys in a fashion that can simultaneously collect information required for a range of indicators it is expected that the main bulk of the data would be collected by cross-sectional surveys conducted though these health facilities and drug outlets. The data should be collected either from drug dispensers/prescribers or patients at drug outlets. It is also very important to consider the procedures that should be followed in order to obtain an adequate sample. However the exact procedures will depend on the data availability and the context of the country. However when assessing sample selection methods it should be presumed that every sample should have an equal possibility of being included into the survey.

By using this approach it will be possible to avoid selection bias and ensure adequate representation of the total population. Nevertheless, in certain cases substantial logistic drawbacks, such as the need for specific skilled workers, budget, time or transportation, may need to be considered when designing the described surveys. Consequently, the best approach for the design of surveys represents a combination of effective statistical methods and data collection techniques (Peacock & Peacock, 2010).

Estimation of the selection of the most important drugs represents the final aspect of assessment and monitoring for the NDP. A range of methods can be employed to monitor trends in prices of drugs. However, a range of principles should be taken into consideration in order to obtain accurate representation of actual consumption of drugs at the national level. Thus, it is necessary to consider the nature of the consumed drugs and their volume. The drugs that should be introduced into the drug list should be selected from the list of the most important, widely used drugs in the country. In the ideal case a National Essential Drugs List would be used to establish the required drugs selection, but unfortunately Kuwait does not have an

Essential Medicines List at present. It is also not possible to obtain a list and volume of the essential drugs at the global level, because in the majority of cases country-specific variables have to be taken into consideration. In an ideal scenario, the prices and the list of all drugs available worldwide should be recorded and assessed; however getting the results would require substantial financial investment. For this reason, it is proposed by the WHO that monitoring is limited to three types**:** (1) Drugs presented in the National Essential Drug List, (2) Therapeutically important drugs, (3) Most widely used drugs (WHO, 2005).

The information above further strengthens the reasons for establishing a NDP for the State of Kuwait because it is an effective solution to the concerns facing the Health Care System; where with the presence of these issues it will be difficult to develop the health sector for the future because they are considered a major obstacle to improving the work of the KMOH. The major health issue in Kuwait at present is a management issue, and specifically the lack of guidelines or a reference for health professionals, and weakness in determining future action plans, which are in line with future needs and requirements. But on the other hand, there are many success factors available for the KMOH to help in developing the Health Care System, such as financial resources, human resources and provision of infrastructure for the establishment of the NDP.

It is proposed through this study that the KMOH can successfully complete this project and avoid obstacles through following the steps mentioned in this Thesis and specifically in this Chapter to;

1. Select a trained qualified staff for the task, where they would work full-time on the project and the KMOH should chose them according to their efficiency, knowledge and training, because the working team will be the foundation stone of the project.

2. Provide the required laws/decrees for establishment of the NDP by presenting an official request to the Kuwaiti Cabinet and Parliament to endorse the establishment of a NDP in Kuwait, and approve the establishment of the Steering Committee – Sub-Committees and a full-time Drug Department to develop, monitor and evaluate the action plan.

3. Carefully follow all the steps relevant to the development of a NDP and don't neglect any stage.

4. Invite all the consumer groups, professional associations, NGOs (Non-governmental organizations), academia, drug sellers, international and local pharmaceutical companies, nurses, pharmacists, doctors and the appropriate Kuwaiti Ministerial members to participate in this National Action.

5. Thoroughly analyse the collected data by local specialists (Steering Committee – Sub-Committees - the Coordination and Monitoring Department for the NDP) and outsourcing foreign experts (if necessary) to verify the results obtained before making decisions on the development of the future plan and strategy for the NDP.

6. Pay attention to efficient implementation and monitoring of the NDP to ensure the success of the project and that it does not falter in the future.

As mentioned earlier, the development of the NDP is the first step of the National Action Plan and the KMOH should not stop at this stage, but maintain continued interest in the implementation and monitoring of the NDP. It is not only important to establish a NDP in Kuwait but also critical that this organization is effective, productive and useful for the Health Care System. The KMOH and the Kuwaiti Government should take benefit from the recommendations, advice and suggestions of the committees and working team, and it is hoped they would support the NDP organisations work financially, administratively and through the media. For example, if the team recommends the establishment of Quality Assurance Departments in Administrations and Hospitals, an Essential Drug List, pharmacovigilance and an individual Drug Administration for the NDP organisation

to manage this organization, and act as the decision-maker and should apply the ideas and developments suggested above on the grounds.

The establishment of a Kuwaiti NDP would lead to the existence of official reference healthcare structure for the KMOH, which can also be useful for other health professionals, local health agencies, researchers, students and persons interested in the Health Care System in Kuwait. The most important benefits from the establishment of the NDP in Kuwait would be the development of professional beneficial structures in pharmaceutical and medical health services, and the reregulating of legislation and regulations (especially as these areas were introduced some time ago); the NDP is also likely to lead into the establishment of several new health projects (such as; Quality Assurance Departments, a Pharmacovigilance Centre, an Essential Drug List and an Electronic Link System between the health areas of the KMOH), which the KMOH needs in order to complete the development and improvement of the Health Care System.

## Chapter 9.0: Conclusion

It is evident from the information provided in the Thesis that the development and implementation of a NDP for every country is very important to promote safe, effective and regulated drug use, and to ensure that quality and appropriate medicines reach the country's population. This is particularly important for nations of the developing world where resources are scarce and access to valuable information is limited and therefore the risks and dangers of irrational drug use are greater. However, such policies are also proven to be extremely useful in countries of the developed world where they can be concerned with combating additional phenomena such as poor quality medicines, counterfeit products, and recreational substance abuse alongside irrational drug use.

Regardless of the particular focus, implementation of National Drug Policies on a global basis with the help of international organizations is of major importance in order to improve the quality of healthcare and consequently improve the health and welfare of millions of people around the world. In carrying this through the international agencies can provide advice and recommendations to a country and especially for the developing countries to establish their NDP.

Establishing a regulated policy for Medicines and Healthcare in a country is fundamental and at present although the Ministry of Health in Kuwait has provided a good support to health for many years, it has been shown in this study that there are a number of areas where there can be improvements in the operation and control of the regulations and processes and the rapid rise in the medicines cost statement each year is of concern. The main method used to keep control of quality, safety and efficacy and the outlay on medicines and the resultant improvements in healthcare in the majority of countries is to have a national policy in place and presently Kuwait does not have such a National Drug Policy (NDP)

and the early part of this Thesis has promoted the importance of development and introduction of a NDP.

The basis of a NDP is promoted by the WHO in conjunction with the World Health Authority and the WHO provides both literature and advice to assist countries who wish to develop a NDP. In addition the support of other countries which have a similar structure, outlook and financial basis can and should be used in providing their experiences in the development, implementation and operation of a NDP in Kuwait.

The research discussed here has justified the need for a NDP, by showing results and information from the interviews with a wide range of health professionals and a number of visits to the Central Medical Stores (CMS), discussions with medicines inspectors, examination of pricing policy, visits to the main receipt points for medicines and the analytical laboratories and discussions with senior officials in the Ministry of Health. Then the research work compared this information with that proposed for a country which is operating a fully functioning NDP.

Once the need for a NDP was demonstrated in the work the next stage was to discuss how the many facets of a NDP could be assembled and reported and the structure of management of development of a NDP and its implementations could be undertaken.

It was found that a number of fundamental issues needed to be addressed, with one of the first being the development and introduction of an Essential Medicines List (EML) as presently Kuwait does not have a priority list of medicines which are both appropriate to the needs of the people, but also provide some control of the number of drugs in different forms and origin which are brought into Kuwait each year. In order to tackle the development of an EML a number of ground rules would be required and a committee established who would examine the needs, clinical

benefits and clinical guidelines, side effects, range of application and cost effectiveness of drug/medicines which could be provided as a priority for public health in the EML. As basic guidance the WHO publishes its own model list of essential medicines, which are specifically limited in number to assist with cost control. The EML committee of the KMOH could start by considering these drugs/medicines and then move forward with a list which is appropriate to its health needs. Putting together an EML will be a major development and will require a number of decisions to be taken which may cause discussion within the health professional groups, however if a NDP is to be successful there needs to be increased control of medicines in Kuwait both in the public and private sector.

By supporting the introduction of a controlled List of medicines it was determined in the studies that in providing health and drug support to the population in Kuwait there are a number of areas where there are problems of direction of the operations and the legislation and regulations presently in place. In operational control terms it was indicated that there are shortages or weakness in the areas of; communication between sections of the KMOH, authority and power of decision making, lack of a well-designed Quality Assurance process in the public pharmaceutical administrations and hospitals in Kuwait, and the absence of Quality Assurance and Service Management Departments in the Laboratories of the Drug and Food Control Administration that test medicines, and investigates suspected illicit drugs. Also testing of medicines as appropriate from the Central Medical Stores, for storage problems and controlling the risk of distributing medicines which are sub-standard, which are then subject to product recall, wastage of money and health risks to the patients in Kuwait.

In establishing a well-structured NDP, the knowledge levels of the staff are very important and the employees involved particularly those in management, those with direct contact with the public and in technical positions have indicated that there is an absence of clear further development programmes in training and

update training for public health professionals in Kuwait. In particular the interviewees indicated that there was an insufficiency and defects in the KMOH training system, and specifically there was no programme for pharmacists to develop their work or to update their clinical and scientific knowledge, this is whether they are working in hospitals, health clinics, health centres or pharmaceutical administrations. It is therefore necessary to development this aspect in Kuwait by carrying out fully structured training programmes for each health area.

It is suggested that the implementation of a NDP in Kuwait could support development of the level of Human Resources (HR) and this can then be reflected positively in a HR Department's work in health care services through supporting an increase in the level of competence of health professionals and especially the senior staff and could lead to a reduction in the need for more staff for health areas and a reduction in medical and administrative errors. It is proposed that there should be a greater role for a Human Resource Development Department and giving them more power and authority to play a primary role in supervising the training of health professionals by providing the necessary training courses, and supporting health professionals in attending local and global conferences.

In order to develop the basis for a NDP, this research provides an outline structure to the issues, how these can be challenged and what can be done to resolve them if a NDP for Kuwait can be agreed . However the process if undertaken will take some time and the organisation of the structures and committees to develop, implement and test the NDP for Kuwait will require much discussion and agreement. The Thesis proposes which committees could be introduced and how these committees could be organised.

Once this section is accepted then the major operation is implementation. It is indicated that there are primary factors affecting the outcome of the NDP implementation. These include the level of financial resources, cooperation

between regional organisations, international organisation and organisations such as the WHO as well as regulation/legislation aspects.

In order to assess the successful introduction of the NDP the requirement of quality indicators is proposed and the Thesis focuses on the use of four main NDP indicators: background assessment, structural, process and outcome indicators. It was suggested that each indicator should be applied in turn and the most important aspects associated with their use are discussed and described. It was also concluded that NDP indicators are highly important for the assessment of the results and alteration of the policy elements, and to reduce the effects of poor results. Thus, based on the data obtained, conclusions could be drawn regarding the effects of the implemented policy and comparisons of the results of the areas of success of implementation of the National Drug Policies in Kuwait. In addition, the monitoring results can also be evaluated and employed by the suggested Coordination and Monitoring Department for the NDP and the Sub-Committees in Kuwait. Thus, it should be possible to form new priorities and make alterations in the drug policy aimed at removing the gaps and difficulties highlighted in the strategy used. Exact NDP development recommendations are expected to vary from country to country, however in the majority of cases it is expected that the appointment of external monitoring organisation may be necessary. It is expected that 3 to 5 years will be necessary to produce and realise an effective National Drug Policy in Kuwait.

This study has shown through the interviews with managers and health professionals that there is an awareness of the issues which need to be addressed if a NDP is to be successful to include the strengthen of the Legislation and Regulations of the drug registration process, stronger penalties to restrain the spread of rule breaking, which should include developments for the reduction of numbers of counterfeit and unregistered drugs in the market and a major reduction

in the high price range and cost variability of medications in the private sector in the State of Kuwait.

In addition the non-existence of a Pharmacovigilance Center in Kuwait causes deficiency of presence of a specialized organization to monitor and follow up the effects of drugs after the completion of registration and the licensing process and a lack of continuing control to examine if a drug has any adverse effects on the patients.

From the studies there was considerable enthusiasm among senior managers (officials in KMOH) to take forward the establishment of a NDP to provide a more efficient and better organized Health System in Kuwait. There are a large number of physicians, pharmacists and specialists in the medical field that have contributed to the study and can have a positive role in the establishment of NDP and help to develop the Health Care System which can contribute so much in improving the human health in Kuwait.

It has been shown that this policy is necessary for the State of Kuwait for several reasons; one of these reasons is to regulate and organize sections of the health system, which have been shown to require updating by re-examining the issues associated with this system and should give the State of Kuwait a health system to support its population. Using interview information revealed through the survey and review of literature, this research project offers proposals and suggestions, which can help find answers to understanding the importance of the National Drug Policy for the State of Kuwait.

In final conclusion it can be stated that the implementation of an effective National Drug Policy in Kuwait is of major importance to the successful development of the country. The information presented in this Thesis indicates that the main purposes of the National Drug Policy are to establish the most important aims, values, aspirations, to outline both medium and long term policy of the government, establish national goals/objectives specifically in the pharmaceutical sector as well as to form primary strategies, by addressing the primary objectives. Therefore it

can be said that the Establishment of a NDP could be one of the most important aspects of future health development in Kuwait.

## Chapter 10.0: References

**Abdo-Rabbo, A., Al-Ansari, M., Gunn, B., and Suleiman, B.** (2009). The Use of Medicines in Oman. Sultan Qaboos Univ Med J *9*, 124–131.

**Abdollahiasl, A., Kebriaeezadeh, A., Dinarvand, R., Abdollahi, M., Cheraghali, A.M., Jaberidoost, M., and Nikfar, S.** (2014). A system dynamics model for national drug policy. Daru *22*, 34.

**Abraham I, MacDonald K** (2012) Clinical Safety of Biosimilar Recombinant Human Erythropoietins. Expert Opin Drug Safe 11: 819-840

**Alali, K** (2011) Establishing of National Drug Policy in the State of Kuwait. Bradford: University of Bradford

**Alamo-Bethencourt, V.** (2008). GSK's Harvard cash injection. Nat. Biotechnol. *956*.

**Alanba Kuwait Newspaper** (2015) The Number of Medical Beds in the Public Sector in Kuwait. Annahar News Paper, [cited 18 Nov 2015]. Available from http://www.alanba.com.kw/ar/kuwait-news/health/563608/06-06-2015

**Al-Halawani, F. & Qawwas, A** (2006) Promoting Rational Drug Use in Jordan, New York: USAID

**Al-Siyabi, K., and Al-Riyami, K.** (2007). Value and types of medicines returned by patients to sultan qaboos university hospital pharmacy, oman. Sultan Qaboos Univ. Med. J. *7*, 109–115.

**Alkhateeb, F.M., Khanfar, N.M., and Clauson, K. a** (2009). Characteristics of physicians who frequently see pharmaceutical sales representatives. J. Hosp. Mark. Public Relations *19*, 2–14.

**Anderson LW, Krathwohl DR** (2001) A Taxonomy for Learning, Teaching and Assessing: A Revision of Bloom's Taxonomy of Educational Objectives. New York: Longman

**Annahal Kuwait Newspaper** (2015) The Number of Medical Beds in the Public Sector in Kuwait. Annahar News Paper, [cited 27 Jul 2015]. Available from http://www.annaharkw.com/annahar/Article.aspx?id=576488&date=27072015

**Babler, S. & Ekins, S** (2010) Pharmaceutical and Biomedical Project Management in a Changing Global Environment (Wiley Series on Technologies for the Pharmaceutical Industry), 1th ed. London: Wiley-Blackwell

**Babor, T. et al.,** (2009) Drug Policy and the Public Good. 11th ed. Oxford: Oxford University Press

**Baggott, R** (2010) Public Health: Policy and Politics. 1th ed. London: Palgrave Macmillan

**Baker, M.** (2016). 1,500 scientists lift the lid on reproducibility. Nature *533*, 452–454.

**Ball, D** (2011) The Regulation of Marks-ups in the Pharmaceutical Supply Chain, Project on medicine prices: WHO/HAT

**Barah F, Morris J & Goncalves V** (2009) Irrational use and poor public beliefs regarding antibiotics in developing countries: a pessimistic example of Syria. *International Journal of Clinical Practice* 63(8): 1263-1264

**Beitz J** (2006) Essential Medicines for Reproductive Health: Guiding Principles for Their Inclusion on National Medicines Lists, Seattle, WA, USA: PATH, 2006, Available:
http://www.path.org/publications/details.php? i=1283 Last accessed: 02/08/2014

**Bennett S, Quick JD & Velásquez G** (1997) Public-private roles in the pharmaceutical sector, Implications for equitable access and rational drug use, Health Economics and Drugs, EDM Series (5), World Health Organization: Geneva

**Bentler, P.M.** (2009). Alpha, dimension-free, and model-based internal consistency reliability. Psychometrika *74*, 137–143.

**Berger, J.S., Brown, D.L., and Becker, R.C.** (2008). Low-Dose Aspirin in Patients with Stable Cardiovascular Disease: A Meta-analysis. Am. J. Med. *121*, 43–49.

**Biddle, I** (2000) Information and Research Skills for Assessment Success. Pascal Press

**Biswas P, Biswas A** (2007) Setting standards for proactive pharmacovigilance in India: The way forward. Indian J Pharmacology; 39:124–8

**Black, W.C** (1990). The cost-effectiveness plane: a graphic representation of cost-effectiveness. Medical Decision Making

**Bolarinwa, O.A.,** 2015. Principles and methods of validity and reliability testing of questionnaires used in social and health science researches. *Nigerian Postgraduate Medical Journal*, *22*(4), p.195.

**Boonyasai RT, Windish DM & Chakraborti** (2007) Effectiveness of teaching quality improvement to clinicians: a systematic review. JAMA; 298v9):1023-1037

**Boutayeb, A., and Boutayeb, S.** (2005). The burden of non communicable diseases in developing countries. Int. J. Equity Health *4*, 2.

**Bowling, A.** (2009) *Research methods in health: investigating health and health services.* London: McGraw-Hill Education

**Boxter v, Santoso B & Edwards, I.R** (2008) International Textbook of Clinical Pharmacology 2nd edition. Sweden: Uppsala Monitoring Centre

**Brienen, M. & Rosen, J** (2015) New Approaches to Drug Policies: A Time For Change. 1th ed. London: Palgrave Macmillan

**Briggs, A., Sculpher, M. & Claxton, K** (2006) Decision Modelling for Health Economic Evaluation (Handbooks for Health Economic Evaluation). 1th ed. Oxford: OUP

**Brower, V.** (2002). Fast tracking drugs to patients. EMBO Rep *3*, 14–16.

**Brown, G.W.** (1982). Standard Deviation, Standard Error. Am. J. Dis. Child. *136*, 937.

**Brudon-Jakobowicz P, Rainhorn JD & Reich MR** (1999) Indicators for monitoring national drug policies - A practical manual, 2nd Edition, World Health Organization, Geneva

**Brudon, P & Dukes, M.N.G.** (1997) Managing drug supply, Chapter 5, National Drug Policies, WHO; management sciences of health MSH, -2nd edition. pp. 56-67, Kumarian Press, Inc, West Hardford, USA (United States of America)

**Brunstein, C.G., Miller, J.S., Cao, Q., McKenna, D.H., Hippen, K.L., Curtsinger, J., Defor, T., Levine, B.L., June, C.H., Rubinstein, P., et al.** (2011). Infusion of ex vivo expanded T regulatory cells in adults transplanted with umbilical cord blood: safety profile and detection kinetics. Blood *117*, 1061–1070.

**Buckley JD, Joyce B, Garcia** (2010) Linking residency training effectiveness to clinical outcomes: a quality improvement approach. Jt Comm J Qual Patient Saf; 36(5):203-208

**Buse, G** (2009) Health Systems Policy, Finance, and Organization. 1st ed. London: Academic Press

**Buse, K., Mays, N. & Walt, G** (2012) Making Health Policy (Understanding Public Health). 2nd ed. London: Open University Press

**Butler C** (2007) "Human Rights and the World Trade Organization: The Right to Essential Medicines and the TRIPS Agreement". Journal of International Law & Policy 5: 1–27

**Button, K.S., Ioannidis, J.P.A., Mokrysz, C., Nosek, B.A., Flint, J., Robinson, E.S.J., and Munafò, M.R.** (2013). Power failure: why small sample size undermines the reliability of neuroscience. Nat. Rev. Neurosci. *14*, 365–376.

**Cabin, R.J., and Mitchell, R.J.** (2000). To Bonferroni or not to Bonferroni: when and how are the questions. Bull. Ecol. Soc. Am. *81*, 246–248.

**Carr, S., Unwin, N. & Pless-Mulloli, T** (2007) An Introduction to Public Health and Epidemiology. 2nd ed. London: Open University Press

**Carrese, J. a, and Rhodes, L. a** (2000). Bridging Cultural Differences in Medical Practice. J. Gen. Intern. Med. *15*, 92–96.

**CDC** (2015). Health, United States, 2015.

**Center for Pharmaceutical Management** (2003) Access to Essential Medicines: Ghana - Prepared for the Strategies for Enhancing Access to Medicines Program, Arlington, VA: Management Sciences for Health

**Central Department of Statistics** (2013) Demography of the State of Kuwait. Available fromhttp://www.cso.gov.kw

**Central Statistical Office** (2013) Kuwait Governmental Online. Available from

http://www.e.gov.kw/sites/Kgoenglish/Portal/Pages/Visitors/AboutKuwait/KuwaitAtaGlane_Population.aspx

**Champagne, F.A.** (2008). Epigenetic mechanisms and the transgenerational effects of maternal care. Front. Neuroendocrinol. *29*, 386–397.

**Chan, I.S., and Ginsburg, G.S.** (2011). Personalized medicine: progress and promise. Annu. Rev. Genomics Hum. Genet. *12*, 217–244.

**Chandy SJ** (2008) Consequences of irrational use of antibiotics. *Indian Journal of Medical Ethics* 5(4): 174-175

**Chaplin, S.** (2014). Uptake of NICE-appraised medicines across the NHS. Prescriber *25*, 31–32.

**Charles M, Bewley-Taylor D & Neidpath A** (2005) Drug Policy in India: Compounding Harm? The Beckley Foundation Drug Policy Programme (BFDPP)

**Chatwin, C** (2011) Drug Policy Harmonization and the European Union. 11th ed. London: Palgrave Macmillan

**Chema, S., and Gathuma, J.M.** (2004). Kenya: the development of private services and the role of the Kenya Veterinary Association. Rev. Sci. Tech. - Off. Int. Des Epizoot. *23*, 331–340.

**Chowdhury, F.R., Ahasan, H.A.M.N., and Rahman, M.M.** (2006). National drug policy of Bangladesh: some pitfalls in implementation. J. Coll. Physicians Surg. JCPSP *16*, 368–370.

**Christensen, K., Doblhammer, G., Rau, R., and Vaupel, J.W.** (2009). Ageing populations: the challenges ahead. Lancet *374*, 1196–1208.

**CICAD** (2009) How to Develop a National Drug Policy: A Guide for policymakers and stakeholders Available from: http://www.cicad.oas.org/en/pubs/How_to_Develop_a_National_Drug_Policy_CICAD_CARICOMA.Pdf

**Clark E** (2008) Counterfeit medicines: the pills that kill. The Telegraph Available: http://www.telegraph.co.uk/health/3354135/Counterfeit-medicines-the-pills-thatkill.htmlLast Accessed: 03/08/14

**Contact** (2006) A publication of the World Council of Churches; Promoting Rational Use of Medicines, 12 (183)

**Cook, A** (2015) Forecasting for the Pharmaceutical Industry, 2nd new ed. London: Gower

**Coulter DM** (2000) The New Zealand intensive medicines monitoring programme in proactive safety surveillance. Pharmacoepidemiol Drug Saf.9:273–80

**Couzin-Frankel, J.** (2013). Cancer Immunotherapy. Science (80-. ). *342*, 1432–1433.

**Coyle YM, Mercer SQ, Murphy-Cullen** (2005) Effectiveness of a graduate medical education programme for improving medical event reporting attitude and behavior. Quality and Safety in Health Care; 14:383-388

**Crombie, I. K & Davis, H.T.O** (1996) Research in health care; design conduct and interpretation of health services Research, pp.288, Wiley, Son Ltd.

**Csikszentmihalyi, M. and Larson, R.,** 2014. Validity and reliability of the experience-sampling method. In *Flow and the foundations of positive psychology* (pp. 35-54). Springer Netherlands.

**Cummings, D.E., and Schwartz, M.W.** (2003). Genetics and pathophysiology of human obesity. Annu. Rev. Med. *54*, 453–471.

**Curtis, M.J., Bond, R.A., Spina, D., Ahluwalia, A., Alexander, S., Giembycz, M.A., Gilchrist, A., Hoyer, D., Insel, P.A., Izzo, A.A. and Lawrence, A.J**., 2015. Experimental design and analysis and their reporting: new guidance for publication in BJP. *British journal of pharmacology*, *172*(14), pp.3461-3471.

**Davies C, English L, Lodwick A, McVeigh J & Bellis MA** (2010) United Kingdom drug situation: annual report to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

**Davis DA, Thomson MA, Oxman AD & Haynes RB** (1995) Changing physician performance: A systematic review of the effect of continuing medical education strategies. Journal of the American Medical Association; 274: 700-705

**Daya, S.** (2003). One-way analysis of variance. Evidence-Based Obstet. Gynecol. *5*, 153–155.

**Deisingh AK** (2005) Pharmaceutical counterfeiting. Analyst 130: 271–9

**Department for International Development (DFID-UK)** (2004) Increasing access to essential medicines in the developing world: UK Government policy and plans

**Després, J.-P., Després, J.-P., Lemieux, I., and Lemieux, I.** (2006). Abdominal obesity and metabolic syndrome. Nature *444*, 881–887.

**DeVries TPGM, Henning R, Hogerzeil HV & Fresle D.A** (1994) Guide to good prescribing - A practical manual, World Health Organization; WHO/DAP/94.11

**Difei Wang, Xinping Zhang** (2011) The selection of essential medicines in China: progress and the way forward, *Southern Med. Review* 4(1) 22-28

**Dikshit R. K, Desai C & Desai M. K** (2008) Pleasures and Pains of running a pharmacovigilance centre Indian Journal of Pharmacology 40(1) s32-34

**Donaldson, L. & Scally, G** (2009) Donaldsons' Essential Public Health. 3rd ed. London: Radcliffe Publishing Ltd

**Dopico, X.C., Evangelou, M., Ferreira, R.C., Guo, H., Pekalski, M.L., Smyth,**

**D.J., Cooper, N., Burren, O.S., Fulford, A.J., Hennig, B.J., et al.** (2015). Widespread seasonal gene expression reveals annual differences in human immunity and physiology. Nat. Commun. *6*, 7000.

**Dorsey P.J, Hellstrom W.J** (2011) the illicit sale of medications for the treatment of erectile dysfunction. Medscape Urology. Available from

http://www.medscape.com/viewarticle/566897 Last Accessed: 03/08/14

**Douglas, J. et al** (2009) A Reader in Promoting Public Health (Published in association with The Open University). 1th ed. London: SAGE Publications Ltd

**Drugs Scope** (2014) Drug Laws Available from: http://www.drugscope.org.uk/resources/drugsearch/drugsearchpages/laws Last Accessed 02/08/14

**Drummond, M. et al** (2005) Methods for the Economic Evaluation of Health Care Programmes. 3rd ed. Oxford: OUP Oxford

**e.gov.kw** (2015) Natural Landscape of the State of Kuwait. Available from

http://www.e.gov.kw/sites/kgoArabic/Pages/Visitors/AboutKuwait/KuwaitAtaGlaneGeographicalLocation.aspx#

**Elmi, A.,** 2013. *Safety of medicines with respect to drug counterfeiting in developing countries* (Doctoral dissertation, Cardiff University).

**El-Shazly, M., Makboul, G., and El-Sayed, A.** (2004). Life expectancy and cause of death in the Kuwaiti population 1987-2000. East. Mediterr. Heal. J. *10*, 45–55.

**EMA** (2011) Applying for EU Marketing Authorisation for Medical Products for Human Use, European Medicines Agency. Available from:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/human_medicines_regulatory.jsp&mid=WC0b01ac058001ff89

**Emanuel, E.J., Schnipper, L.E., Kamin, D.Y., Levinson, J., and Lichter, A.S.** (2003). The costs of conducting clinical research. J. Clin. Oncol. *21*, 4145–4150.

**Epstein AM** (2008) Performance measurement and professional improvement: approaches, opportunities and challenges. Health Systems, Health and Wealth. WHO Ministerial Conference on Health Systems

**Essential drug supply chain. Available from**: http://www.meds.or.ke/index.php.

**European Commission** (2008) Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector. Available from: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1924&format=HTML&aged=1&language=en&guiLanguage=en Last accessed: 03/08/2014

**European Monitoring Centre for Drug and Drug Addiction** (2012) Data: Statistical Bulletin 2012 Available: http://www.emcdda.europa.eu/stats12 Last Accessed 02/08/014

**Eween, M** (2010) Medicine Prices, Availability, Affordability and Price Components, Coordinator, global Projects (pricing), Health action international. WHO, WIPO and WTO Joint Technical Symposium

**Executive Agency for Health and Consumers** (2009) Pharmacovigilance for Patients & Consumers Available: http://www.haiweb.org/19072009/19July2009FactsheetTheEuropeanCommission's ProposalforaPharmacovigilanceDirective.pdf Last Accessed: 03/08/14

**Executive Office of the President of the United States** (2015) National Drug Control Strategy: 2011. 1th ed. New York: CreateSpace Independent Publishing Platform

**Faraggi, D., and Reiser, B.** (2002). Estimation of the area under the ROC curve. Stat. Med. *21*, 3093–3106.

**Faul, F., Erdfelder, E., Buchner, A., and Lang, A.-G.** (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. Behav. Res. Methods *41*, 1149–1160.

**FDA** (2009) FDA Initiative to Combat Counterfeit Drugs FDA U.S Food and Drug Administration Available: http://www.fda.gov/drugs/drugsafety/ucm180899.htm Last Accessed: 03/08/14

**FDA** (2011) Information for Consumers. Available from

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143558.htm

**Federal Ministry of Health** (2003) National Drug Policy, Geneva: World Health Organisation

**Feig, C., Jones, J.O., Kraman, M., Wells, R.J.B., Deonarine, A., Chan, D.S., Connell, C.M., Roberts, E.W., Zhao, Q., Caballero, O.L., et al.** (2013). Targeting CXCL12 from FAP-expressing carcinoma- associated fi broblasts synergizes with anti – PD-L1 immunotherapy in pancreatic cancer. Proc Natl Acad Sci U S A *110*, 20212–20217.

**Fernandopulle RB, Weerasuriya K** (2003) what can consumer adverse drug reaction reporting add to existing health professional-based systems? Focus on the developing world. Drug Safe 26: 219-225

**Finklea KM** (2010) Reauthorizing the Office of National Drug Control Policy: Issues for Consideration, Congressional Research Service Report R41535

**Food and Drugs Authority,** 2015. Working for your safety. Ghana. Available from: http://www.fdaghana.gov.gh/

**Ford N** (2003) Patents, access to medicines and the role of non-governmental organizations. *Journal of Generic Medicines* 1: 137

**Fresle, D. & Wolfheim, C** (1997) Public education in rational drug use, Geneva: World Health Organisation

**Gates, Sr.,** 2003. The Bill & Melinda Gates Foundation Announces US$2 Million in New Grants for HIV/AIDS Prevention in Kenya. Available from: http://www.gatesfoundation.org/Media-Center/Press-Releases/2002/03/HIVAIDS-Prevention-in-Kenya.

**Gerald,M.C.** (1991) National drug policy and rational use: A model curriculum for developing countries. Article Journal of Clinical Epidemiology, 45 (2), 95-99.

**Ghana National Drugs Programme (GNDP) Ministry of Health** (2004) Ghana National Drug Policy 2nd Edition

**Ghinea, N., Lipworth, W., and Kerridge, I.** (2016). Propaganda or the cost of innovation? Challenging the high price of new drugs. BMJ i1284.

**Ghosh, S., Palmer, S.M., Rodrigues, N.R., Cordell, H.J., Hearne, C.M., Cornall, R.J., Prins, J.B., McShane, P., Lathrop, G.M., and Peterson, L.B.** (1993). Polygenic control of autoimmune diabetes in nonobese diabetic mice. Nat. Genet. *4*, 404–409.

**Gibb S** (2011) Human Resource Development Edinburgh Business School, Heriot-Watt University: Edinburgh pp 1-30

**Glen, K** (2012) Apply standard procedures for Drug inspectors, contributed. Available from: http://www.ideaconnection.com/solutions/known/666-Apply-standard-procedures-for-drug-inspectors.html

**Glied, S. & Smith, P** (2013) The Oxford Handbook of Health Economics (Oxford Handbooks in Economics). Reprint ed. Oxford: OUP

**Goldacre, B** (2014) Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients.

Reprint ed, London: Faber & Faber

**Gordon L, Tinsley L, Godfrey C & Parrott S** (2006) *The economic and social costs of Class A drug use in England and Wales, 2003/04,* In Singleton N, Murray R, and Tinsley L, (eds) 'Measuring different aspects of problem drug use: methodological developments.' Home Office Online Report 16/06

**Gottlieb, S.** (2000). Companies reduce prices for HIV drugs in developing countries. Bull. World Health Organ. *78*, 862.

**Green, A.** (2013). Africa's clinical trial: Big Pharma deploys R&D in Africa. This Is Africa http://www.thisisafricaonline.com/News/Africa-s-cl.

**GREEN , J. & THOROGOOD, N**. 2004. *Qualitative methods for health research,* London, SAGE.

**Green, S.** (2008). Ethics and the pharmaceutical industry. Australas. Psychiatry *16*, 158–165.

**GSK announces new strategic investments in Africa to increase access to medicines build capacity and deliver sustainable growth. 2014**. Available from: https://us.gsk.com/en-us/media/press-releases/2014/gsk-announces-new-strategic-investments-in-africa-to-increase-access-to-medicines-build-capacity-and-deliver-sustainable-growth.

**Guest, C., Ricciardi, W., Kawachi, I. & Lang, I** (2013) Oxford Handbook of Public Health Practice (Oxford Medical Handbooks). 1th ed. London: OUP Oxford

**Guinness, I** (2011) Introduction to Health Economics (Understanding Public Health). 2nd ed. London: Open University Press

**Gupta RK** (2005) Essential Medicines: Where We Stand Today, *JK Science*; 7(1)

**Gyngell K** (2011) The UK's Treatment War on Drugs: A Lesson in Unintended Consequences and Perverse Outcomes, *The Journal of Global Drug Policy and Practice*

**Halpern, D.F** (2002) Thinking Critically about Thinking Critically, 4th edn. Mahwah, NJ: Lawrence Erlbaum Associates

**Harpwood, V.** (2016). Law and ethics in medicine. Med. (United Kingdom) *44*, 619–622.

**Hashemite Kingdom of Jordan** (2002) National Drug Policy. National Drug Policy Management & Implementation Department, Amman: Jordan Ministry of Health

**Hassett, V** (2012) Know How to Spot Counterfeit Drugs. Available from

http://www.ideaconnection.com/solutions/known/290-Know-how-to-spot-counterfeit-drugs.html

**Hawkins, L** (2011) Project on Medicine Prices and Availability, Review Series on Pharmaceutical Pricing Policies and Interventions, WHO/HAI working paper 4

**Health Foundation** (2012) Quality Improvement Training for Healthcare Professionals the Health Foundation: Inspiring improvement Available from: http://www.health.org.uk/public/cms/75/76/313/3731/Quality%20improvement%20training%20for%20healthcare%20professionals.pdf?realName=XZlZmh.pdf Last Accessed: 03/08/14

**Hellerstein, R** (2011) What Do Drug Monopolies Cost Consumers in Developing Countries?, New York: Federal Researve Bank

**Hill H** (2005) Counterfeit medicines – how much of a risk to public health are they? Pharm J 275: 520

**Hill S , Johson, K** (2004) Emerging challenges and opportunities in drug registration and regulation in developing countries

**HN Proficiency Testing Inc** (2014) what is Proficiency Testing? HN Proficiency Testing INC. Available: http://www.hn-proficiency.com/profi.htm Last Accessed: 03/08/14

**Hoebert, J.M., van Dijk, L., Mantel-Teeuwisse, A.K., Leufkens, H.G., Laing, R.O., Kanji, N., Hardon, A., Harnmeijer, J., Mamdani, M., Walt, G., et al.** (2013). National medicines policies – a review of the evolution and development processes. J. Pharm. Policy Pract. *6*, 5.

**Hogerziel HV** (1995) Promoting rational prescribing: an international perspective. *British Journal of Clinical Pharmacy* 39:1-6

**Hogerzeil, H. V** (2004). The concept of essential medicines: lessons for rich countries. BMJ Br. Med. J. *329*, 1169–1172.

**Hoskins B** (2012) *Chapter 1: Laboratory Quality Assurance Programs* Cooperative Bulletin Number 493 pp 1-10

**Hutchings J, Neroutsos K & Donnelly K** (2010) Making the List: The Role of Essential Medicines Lists in Reproductive Health, *International Perspectives on Sexual and Reproductive Health*; 36(4): 205-208

**Hutin Y.J.F, Hauri A.M & Armstrong G.L** (2003) Use of injections in healthcare settings worldwide, 2000: literature review and regional estimates. *British Medical Journal* 327(7423): 1075

**IFPMA** (2014) The pharmaceutical industry and global health: facts and figures, London: International Pharmaceutical Manufacturers & Associations

**Imber S** (2014) European Parliament Votes To Strengthen Customs Powers To Seize Counterfeit Drugs In Transit. The Partnership for Safe Medicines Available from:http://www.safemedicines.org/2014/03/european-parliament-votes-to-strength-customs-powers-to-seize-counterfeit-drugs-in-transit-3-4-14.htmlLast Accessed: 03/08/14

**India Ministry of Health and Family Welfare (IMHFW)** (2010) National Drug Policy on Malaria

**INRUD** (2003) Inrud News, Newsletter of the International Network for Rational Use of Drugs. 13 (1)

**Inter-American Drug Abuse Control Commission (CICAD) - Organization of American States (OAS)** (2009) How to Develop a National Drug Policy: A Guide for Policymakers, Practitioners and Stakeholders

**Ioannidis, J.P.A. (2007).** Why most published research findings are false: Author's reply to Goodman and Greenland [7]. PLoS Med. *4*, 1132–1133.

**Ioannidis J.P.A, Lau J** (2001) Completeness of safety reporting in randomized trials: An evaluation of 7 medical areas. Journal of the American Medical Association 285 (4): 437-443

**IPC Group** (1999) Operational principles for good pharmaceutical procurement. 1th ed. Geneva: World Health Organisation

**Jackson, D** (2012) Healthcare Economics Made Easy. 1th ed. London: Scion Publishing Ltd

**Jackson G, Arver S, Banks I & Stecher VJ** (2010) Counterfeit phosphodiesterase type 5 inhibitors pose significant safety risks. Int J Clin Pract; 64: 497–504

**Jacobsen, T. & Wertheimer, A** (2009) Modern Pharmaceutical Industry. 1st ed. London: Jones and Bartlett Publishers, Inc

**Jaffar, S. and World Health Organization,** 2011. Pharmaceutical Sector Country Profile Questionnaire. Oman.

**Joshi SR** (2011) Biosimilar peptides: need for pharmacovigilance. J Assoc Physicians India 59: 44-47

**Jarboe, J., Gupta, A., and Saif, W.** (2014). Therapeutic human monoclonal antibodies against cancer. Methods Mol. Biol. *1060*, 61–77.

**Jeruto, P., Lukhoba, C., Ouma, G., Otieno, D., and Mutai, C.** (2008). An ethnobotanical study of medicinal plants used by the Nandi people in Kenya. J. Ethnopharmacol. *116*, 370–376.

**Johnson, J.R., Ning, Y.M., Farrell, A., Justice, R., Keegan, P., and Pazdur, R.** (2011). Accelerated approval of oncology products: The food and drug administration experience. J. Natl. Cancer Inst. *103*, 636–644.

**Kabene S. M, Orchard C, Howard J. M, Soriano M.A & Leduc R,** (2006) The importance of human resources management in health care: a global context Human Resources Health 4(20)

**Kaplan, W., and Laing, R.** (2003). Paying for pharmaceutical registration in developing countries. Health Policy Plan. *18*, 237248.

**Kareru, P.G., Kenji, G.M., Gachanja, A.N., Keriko, J.M., and Mungai, G.** (2007). Traditional medicines among the Embu and Mbeere peoples of Kenya. African J. Tradit. Complement. Altern. Med. *4*, 75–86.

**Kassaye K.D, Amberbir A, Getachew B & Mussema Y** (2006) A historical overview of traditional medicine practices and policy in Ethiopia, *Ethiop. J. Health Dev.*; 20(2) 127-134

**Kenya National Drug Policy** (1994). Available from

http://apps.who.int/medicinedocs/documents/s16443e/s16443e.pdf

**Khoja, T.A.M., and Bawazir, S.A.** (2005). Group purchasing of pharmaceuticals and medical supplies by the Gulf Cooperation Council states. East. Mediterr. Heal. J. *11*, 217–225.

**Kilpatric,G** (2002) Definitions of Public Policy and the Law Contributed. National Violence Against Women Prevention Research Centre. Available from

www.musc.edu/vawprevention/policy/definition.shtml - United States

**Kim, T.K.,** 2015. T test as a parametric statistic. *Korean journal of anesthesiology*, *68*(6), pp.540-546.

**Krumholz, H.M., Ross, J.S., Presler, A.H., and Egilman, D.S.** (2007). What Have We Learnt from Vioxx? Br. Med. J. *334*, 120–123.

**Kuanpoth, J** (2010) Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future. 1st ed. London: Edward Elgar Publishing Ltd

**Kumar V** (2013) Challenges and Future Consideration for Pharmacovigilance Journal of Pharmacovigilance 102 (1)

**Kuwait country profile (2001).** Available At: http://www.emro.who.int/mnh/whd/CountryProfile-KUW.htm

**Kuwait Pharmacy Association** (2015) The Number of Pharmacists working in Kuwait Ministry of Health. Kuwait Pharmacy Association

**Kuwait info.** About the country, its history, culture, business atmosphere, and political scene.

Available from

www.kuwait-info.com/ - Cached- Block all www.kuwait-info.com results

**Kuwaiti Ministry of Health** (2013 f) Central Medical Stores Administration. KMOH

**Kuwaiti Ministry of Health** (2011 g) Department of Private Inspection of Drug Inspection Administration. KMOH

**Kuwaiti Ministry of Health** (2013 k) The Difference in Cost between Patent Drugs and Generic Drugs which the KMOH Purchased in 20012-2013. KMOH

**Kuwaiti Ministry of Health** (2011 b) Drug and Food Control Administration. KMOH

**Kuwaiti Ministry of Health** (2011 f) Drug Inspection Administration in Kuwait. KMOH

**Kuwaiti Ministry of Health** (2014 h) Drug Release Office in Kuwait International Airport. KMOH

**Kuwaiti Ministry of Health** (2014 k) Drug Supervision of Central Medical Store Administration. KMOH

**Kuwaiti Ministry of Health** (2014 i) Inspection supervision of Drug Inspection Administration. KMOH

**Kuwaiti Ministry of Health** (2013 i) Number of Large Irregularities of the Private Pharmacies in Kuwait During Morning Inspection Period in 2013. KMOH

**Kuwaiti Ministry of Health** (2013 j) Number of Large Irregularities of the Private Pharmacies in Kuwait During Night Inspection Period in 2013. KMOH

**Kuwaiti Ministry of Health** (2011 n) Organization Structure of Central Medical Stores. KMOH

**Kuwaiti Ministry of Health** (2015 d) Organization Structure of Drug and Food Control Administration. KMOH

**Kuwaiti Ministry of Health** (2011 j) Organization Structure of Drug Inspection Administration. KMOH

**Kuwaiti Ministry of Health** (2011 c) Organization Structure of Pharmaceutical Services Administration. KMOH

**Kuwaiti Ministry of Health** (2011 b) Pharmaceutical Services Administration. KMOH

**Kuwaiti Ministry of Health** (2013 a) The Bed Utilization Indices in MOH Hospitals. KMOH

**Kuwaiti Ministry of Health** (2015 l) Comparison in prices of the same drugs in private market between Kuwait and KSA in 2015. KMOH

**Kuwaiti Ministry of Health** (2013 h) The Cost of Expired Drugs in CMS from 01/01/2013 to 31/12/2013. KMOH

**Kuwaiti Ministry of Health** (2011 h) The Department of Herbal and Veterinary Inspection. KMOH

**Kuwaiti Ministry of Health** (2015 i) The Distribution Drug Cycle in the Central Medical Stores. KMOH

**Kuwaiti Ministry of Health** (2011 f) The Drug Pricing Department of Drug and Food Control Administration. KMOH

**Kuwaiti Ministry of Health** (2014 f) The Drug Pricing Department of Drug and Food Control Administration. KMOH

**Kuwaiti Ministry of Health** (2011 k) The Drug Supervision. KMOH

**Kuwaiti Ministry of Health** (2015 k) The Expected Number of the Private Pharmacies in Kuwait. KMOH

**Kuwaiti Ministry of Health** (2011 m) The Finance Supervision of Central Medical Stores Administration. KMOH

**Kuwaiti Ministry of Health** (2014 o) The Finance Supervision of Central Medical Stores Administration. KMOH

**Kuwaiti Ministry of Health** (2015 a) The General Budget of the Kuwaiti Ministry of Health Since 2004 to 2015. KMOH

**Kuwaiti Ministry of Health** (2015 b) The Health Field in Kuwait Needs More Trained Health Professionals. KMOH

**Kuwaiti Ministry of Health** (2011 e) The Laboratories Supervision. KMOH

**Kuwaiti Ministry of Health** (2014 n) The Laboratories Supervision of Central Medical Stores Administration. KMOH

**Kuwaiti Ministry of Health** (2011 l) The Medical Supplies Supervision of Central Medical Store Administration. KMOH

**Kuwaiti Ministry of Health** (2014 m) The Medical Supplies Supervision of Central Medical Store Administration. KMOH

**Kuwaiti Ministry of Health** (2014 a) The Number Difference of the Pharmacists per Nationality in the Ministry of Health. KMOH

**Kuwaiti Ministry of Health** (2013 d) The Number of Beds in Private Health Centers in Kuwait. KMOH

**Kuwaiti Ministry of Health** (2015 c) The Number of Health Facilities in Public Sector. KMOH

**Kuwaiti Ministry of Health** (2014 d) The Number of Pharmacies in Public Health Clinics in State of Kuwait to 9/1/2014. KMOH

**Kuwaiti Ministry of Health** (2014 c) The Number of Pharmacies in Public Hospitals in State of Kuwait to 9/1/2014. KMOH

**Kuwaiti Ministry of Health** (2014 j) The Numbers of the Health Professionals Who are Working in Central Medical Store Administration. KMOH

**Kuwaiti Ministry of Health** (2015 j) The Number of the Private Pharmacies in State of Kuwait to 2015. KMOH

**Kuwaiti Ministry of Health** (2014 b) The Number of the Required Health Professionals Working in MOH from 2010 – 2014. KMOH

**Kuwaiti Ministry of Health** (2015 f) The Organization Structure of the Registration and Release Supervision. KMOH

**Kuwaiti Ministry of Health** (2015 g) The Purchasing Drug Cycle in the Central Medical Stores. KMOH

**Kuwaiti Ministry of Health** (2014 g) The Quality Assurance (QA) Department of Drug and Food Control Administration. KMOH

**Kuwaiti Ministry of Health** (2013 c) The Quantity of Beds in Private Hospitals Within the State of Kuwait in 2013. KMOH

**Kuwaiti Ministry of Health** (2013 b) The Quantity of Medical Institutions in Private Medical Sector Within the state of Kuwait in 2013. KMOH

**Kuwaiti Ministry of Health** (2015 e) The Registration and Release Supervision. KMOH

**Kuwaiti Ministry of Health** (2015 h) The Storage Drug Cycle in the Central Medical Store. KMOH

**Kuwaiti Ministry of Health** (2013 g) The Store Supervision of Central Medical Store Administration. KMOH

**Kuwaiti Ministry of Health** (2011 a) The Structure of Pharmaceutical Sector for the Ministry of Health. KMOH

**Kuwaiti Ministry of Health** (2011 i) The Supervision of Licensed Materials, Narcotics and Psychotropic Substances. KMOH

**Kuwaiti Ministry of Health** (2013 e) The Total Number of All Inspection Visits to the Private Pharmacies and Public/Private stores in 2013. KMOH

**Kuwaiti Ministry of Health** (2012 a) The Trade Penalties for the Private Sector in Kuwait. KMOH

**Kuwaiti Ministry of Health** (2014 e) Training Program. KMOH

**Kuwait University** (1998) Health Care System in Kuwait. Kuwait University . Available from

http://pubcouncil.kuniv.edu.kw/jgaps/homear.aspx?id=8&Root=yes&authid=434

**Kwiatkowski, D.P.** (2005). How malaria has affected the human genome and what human genetics can teach us about malaria. Am. J. Hum. Genet. *77*, 171–192.

**Lancet** (2010) The Lancet Oncology, 375 (9731), 2052

**Landers, E.** (2017). Trump pledges to work with Big Pharma to lower drug prices.

**Laing, R.** (1991). Essential drugs programmes in Africa. Afr. Health *14*, 32–33.

**Laing R.O, Hogerzeil H.V & Ross-Degnan D** (2001) Ten recommendations to improve use of medicines in developing countries, *Health Policy and Planning*; 16(1): 13-20

**Lee J.F, Litten J.B & Grampp G** (2012) Comparability and bio similarity: considerations for the healthcare provider. Curr Med Res Opin 28: 1053-1058

**Lee, M** (1994) The politics of pharmaceutical reform: the case of the Philippines National Drug Policy. International Journal of Health Services, Volume 4, pp. 477-494

**Le Grand A, Hogerzeil H.V & Haaijer-Ruskamp F.M** (1999) Intervention research in rational use of drugs: a review. *Health Policy and Planning* 14(2): 89-102

**Leung, E.Y.L., Malick, S.M., and Khan, K.S.** (2013). On-the-job evidence-based medicine training for clinician-scientists of the next generation. Clin. Biochem. Rev. *34*, 93–103.

**Levy, H., and Meltzer, D.** (2008). The impact of health insurance on health. Annu. Rev. Public Health *29*, 399–409.

**Lewis, G., Sheringham, J., Kalim, K. & Crayford, T** (2008) Mastering Public Health: A postgraduate guide to examinations and revalidation: A Guide to Examinations and Revalidation ( MFPH ). 11th ed. Cambridge: CRC Press

**Licata A, Macaluso F.S & Craxì A** (2013) Herbal hepatotoxicity: a hidden epidemic. Intern Emerg Med 8: 13-22

**Liston, A.** (2008). Autoimmunity: beyond the immune system. Immunol. Cell Biol. *86*, 295–296.

**Mackay, I.M., and Arden, K.E.** (2015). MERS coronavirus: diagnostics, epidemiology and transmission. Virol. J. *12*, 222.

**Main, M.E. and Ogaz, V.L.,** (2016) Common Statistical Tests and Interpretation in Nursing Research. *International Journal of Faith Community Nursing*, *2*(3), p.5.

**Management Sciences for Health (MSH)** (2001) Improving Drug Management to Control Tuberculosis, *The Manager* (Boston); 10(4): 1-22

**Management Sciences for Health (MSH), Euro Health Group (EHG)** (1997) The Selection, Procurement, Distribution, and Use of Pharmaceuticals. In: Edditor of MS. (2nd Rev Sub Ed) Kumarian Press Books on International Development conjunction with the WHO, PP 161-407

**Manchikanti L** (2007) National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies, Pain Physician; 10: 399-424

**Martinez-Guarneros, Balandrano-Campos S, Solano-Ceh MA, Gonzalez-Dominguez F, Lipman HB, Ridderhof JC, Flisser A** (2003) Implementation of proficiency testing in conjunction with a rechecking system for external quality assurance in tuberculosis laboratories in Mexico. International Journal of Tuberculosis Lung Disease 7(6) pp. 516-521

**Marx, V.** (2013). Biology: The big challenges of big data. Nature *498*, 255–260.

**Mayo, A**. (2014). Improving medical education in Kenya: an international collaboration. J Med Libr Assoc *102*, 96–100.

**Mckee, M** (2011) Issues in Public Health (Understanding Public Health). 2nd ed. London: Open University Press

**Mhamba R.M, Mbirigenda S** (2010) The drugs industry and access to essential medicines in Tanzania, *EQUINET Discussion Paper Series 83* Training and Research Support Centre, SEATINI, Rhodes University, EQUINET: Harare

**MHRA** (2010) Counterfeit medicines and devices. Medicines and Healthcare Products Regulatory Agency. Available from http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Counterfeitmedicinesanddevices/index.htm Last Accessed: 03/08/14

**MHRA** (2011) Good Distribution Practice MHRA: Regulating Medicines and Medical Devices Available from: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodDistributionPractice/ Last Accessed: 03/08/14

**MHRA** (2013) Advice and information for consumers Medicines and Healthcare Products Regulatory Agency. Counterfeit medicines and devices. Available from: http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/ Last Accessed: 03/08/14

**MHRA** (2013) Pharmacovigilance - How we monitor the safety of medicines Availablefrom: http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/Pharmacovigilance/index.htm#3 Last Accessed: 03/08/14

**Miller V, Nwokike J & Stergachis A** (2012) Pharmacovigilance and global HIV/AIDS. Curr Opin HIV AIDS 7: 299-304

**Ministry of Health of Ghana** (2004) Ghana National Drug Policy, [July 2004]. Available from: apps.who.int/medicinedocs/documents/s16185e/s16185e.pdf

**Ministry of Health of Kuwait** (2010) The Organization Structure of Pharmaceutical Sector for the Kuwaiti Ministry of Health.

**Ministry of Health, R. of K.** (1994). The Kenya National Drug Policy.

**Ministry of Health, S. of O.** (2000). Oman National Drug Policy.

**Ministry of Health and Social Services, N.** (1998). National Drug Policy for Namibia.

**Ministry for Health and Social Services** (1998) Namibia National Drug Policy, [August 1998]. Available from: www.healthnet.org.na/.../policies/National%20Drug%20Policy.pdf

**Miralles, M., Aboagye-Nyame, F., Arhinful, D., Barraclough, A., Briggs, J., Broun, D., Janvier, M., Lalvani, P., Moore, T., Ofori-Adjei, D., et al.** (2003). Access to Essential Medicines: Ghana.

**Mondaq** (2012) Ukraine: Responsibility For Counterfeit Drug Is Strengthened. Mondaq: Connecting knowledge & People Available from: http://www.mondaq.com/x/198224/Healthcare/Responsibility+For+Counterfeit+Drug+Is+Strengthened Last Accessed: 03/08/14

**Morgan, S., McMahon, M., and Greyson, D.** (2008). Balancing health and industrial policy objectives in the pharmaceutical sector: Lessons from Australia. Health Policy (New. York). *87*, 133–145.

**Morris, S., Devlin, N., Parkin, D. & Spencer, A** (2012) Economic Analysis in Healthcare. 2nd ed. London: John Wiley & Sons

**Moynihan, R., Heath, I., and Henry, D.** (2002). Selling sickness: the pharmaceutical industry and disease mongering. BMJ *324*, 886–891. Parliament, Houses of, U. (2010). Drug Pricing.

**MSC** (2011) Establishing of National Drug Polict in the State of Kuwait. Bradford: University of Bradford

**MSH** (2005) Rapid pharmaceutical management assessment: an indicator-based approach. 1th ed. Washington: Management Sciences for Health

**MSH/RPM** (1995) Rapid pharmaceutical management assessment: an indicator-based approach, Management Sciences for Health, Rapid Pharmaceutical Management Project

**Murphy, E. A. and Dingwall, R.** (2003) *Qualitative methods and health policy research.* New York: Transaction Publishers

**National Institute for Health and Clinical Excellence** (2008) Guide to the methods of technology appraisal, [last accessed 31 October 2008]. Available from: www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf

**Nature Medicine** (2010) lay down the law on fakes. Nat Med; 16: 348.Ogrinc G, Headrick LA, Mutha S (2003) A framework for teaching medical students and residents about practice-based learning and improvement, synthesized from a literature review. Acad Med; 78:748-753

**Nigeria Federal Ministry of Health (NFMH) and World Health Organization** (2005) National Drug Policy 1st Revision

**Nikfar S, Kebriaeezadeh A, Majdzadeh R & Abdollahi M** (2005) Monitoring of National Drug Policy (NDP) and its standardized indicators; conformity to decisions of the national drug selecting committee in Iran, *BMC International Health and Human Rights;* 5(5)

**Normad, C. & Weber, A** (1998) Social health insurance: a guidebook for planning. 2nd ed. Geneva: World Health Organisation

**Observatory, A.H.** (2017). Combat HIV/AIDS, TB, malaria and other diseases.

**Odhiambo, J.O., Kellogg, T.A., Kim, A.A., Ng'ang'a, L., Mukui, I., Umuro, M., Mohammed, I., De Cock, K.M., Kimanga, D.O., and Schwarcz, S.** (2014). Antiretroviral treatment scale-up among persons living with HIV in Kenya: results from a nationally representative survey. J. Acquir. Immune Defic. Syndr. *66 Suppl 1*, S116-22.

**Okada, H., Kuhn, C., Feillet, H., and Bach, J.F.** (2010). The "hygiene hypothesis" for autoimmune and allergic diseases: An update. Clin. Exp. Immunol. *160*, 1–9.

**O'Leary, Z.** (2004) *The essential guide to doing research.* London: Sage Legard

**Olof B, Carlsson S, Tusic M, Olsson R, Franzen L & Hulten P** (2014) Laboratory and clinical evaluation of on-site urine drug testing Scandinavian Journal of Clinical & Laboratory Investigation Online Publication Available from: http://informahealthcare.com/doi/abs/10.3109/00365513.2014.939995 Last Accessed: 03/08/14

**Olsson S** (1998) The role of the WHO Programme for International Drug Monitoring in coordinating worldwide drug safety efforts. Drug Saf. ; 19:1–10

**Omani National Drug Policy Survey** (2003) World Health Organization, WHO/EDM/DAP/`2004.1

**Parkin, D** (2009) Techniques of Economic Appraisal. Including cost-effectiveness analysis and modelling, cost-utility analysis, option appraisal and cost-benefit analysis, the measurement of health benefits in terms of QALYs and related measures e.g. DALYs. Health Economics: 5 Techniques of Economic Appraisal

**Parliament, Houses of, UK.** (2010). Drug Pricing.

**PATH, the World Health Organization, and the United Nations Population Fund** (2006) Essential Medicines for Reproductive Health: Guiding Principles for Their Inclusion on National Medicines Lists, PATH (Seattle)

**PATTON, M** (1990): *Qualitative Evaluation and Research Methods*, Sage Publications

**Peacock, J. & Peacock, P** (2010) Oxford Handbook of Medical Statistics (Oxford Medical Handbooks). 1st ed. Oxford: OUP Oxford

**Phanouvong, S.,** 2008. Rapid Assessment of Medicines Quality Assurance Activities in a Pharmaceutical Supply System: a Checklist for Ensuring Product Quality.

**Pharmacy and Poisons Board: Registration and Enrollment. Kenya**. Available from: http://pharmacyboardkenya.org/?p=527).

**Physician Leadership on National Drug Policy (PLNDP)** (2002) Adolescent Substance Abuse: A Public Health Priority - An evidence-based, comprehensive and integrative approach

**Pope, C., Ziebland, S., and Mays, N.** (2006) Analysing qualitative data. In: Pope, C., And Mays, N. (Ed.) *Quality in Qualitative Health Research, in Qualitative Research in Health Care, Third Edition.* Oxford, UK: Blackwell Publishing Ltd,, pp. 63-81

**Radovanovic, Z.** (1994). Mortality patterns in Kuwait: Inferences from death certificate data. Eur. J. Epidemiol. *10*, 733–736.

**Rainhorn JD, Brudon-Jakobowicz P & Reich M.R** (1994) Priorities for pharmaceutical policies in developing countries: results of a Delphi survey, *Bulletin of the World Health Organization*; 72(2): 257-264

**Ratanawijitrasin, S., Soumerai, S., and Weerasuriya, K.** (2001). Do national medicinal drug policies and essential drug programs improve drug use?: a review of experiences in developing countries. Soc Sci Med *53*, 831–844.

**Ray, W., and Stein, C.** (2006). Reform of drug regulation--beyond an independent drug-safety board. N Engl J Med *354*, 194–201.

**Reich M.R,** (1987) Essential Drugs: Economics and politics in international health, *Health Policy*; 8: 39-57

**Reich, M** (1994) Bangladesh pharmaceutical policy and politics. Health Policy and Planning, 9(2), pp. 130-143

**Reuter, P., and Caulkins, J.P.** (1995). Redefining the goals of national drug policy: Recommendations from a working group. Am. J. Public Health *85*, 1059–1063.

**Reuter P, Stevens A** (2007) An Analysis of UK Drug Policy - A Monograph Prepared for the UK Drug Policy Commission (UKDPC)

**Rockefeller Foundation** (2003) Human Resources for Health and Development: A joint learning initiative. Global Health Trust Pamphlet from Rockefeller Foundation pp.1 – 13

**Roederer, M., Quaye, L., Mangino, M., Beddall, M.H., Mahnke, Y., Chattopadhyay, P., Tosi, I., Napolitano, L., Terranova Barberio, M., Menni, C., et al.** (2015). The genetic architecture of the human immune system: A bioresource for autoimmunity and disease pathogenesis. Cell *161*, 387–403.

**Roise, A** (2012) Molecular Pharmaceutical Authentication using EDXRD Technology Contributed. XStream Systems, Inc. Available from:

http://www.ideaconnection.com/solutions/known/894-Molecular-Pharmaceutical-Authentication-using-EDXRD-T.html

**Schneider, H., Blaauw, D., Gilson, L., Chabikuli, N., and Goudge, J.** (2006). Health Systems and Access to Antiretroviral Drugs for HIV in Southern Africa: Service Delivery and Human Resources Challenges. Reprod. Health Matters *14*, 12–23.

**Schuhmacher, A., Gassmann, O., and Hinder, M.** (2016). Changing R&D models in research-based pharmaceutical companies. J. Transl. Med. *14*, 1–11.

**Schweitzer, S** (2006) Pharmaceutical Economics and Policy. 1st ed. London: Oxford University Press

**Sedgwick, P.** (2014). Spearman's rank correlation coefficient. BMJ *349*, g7327.

**Seize, T.K.** (1977). Student's t-test. South. Med. J. *70*, 1299.

**Seoane-Vazquez E, Rodriguez-Monguio R** (2010) Access to essential drugs in Guyana: a public health challenge, *Int. J. Health Plann. Mgmt.*; 25: 2-16

**Shabsigh R, Perelman M.A, Laumann EO & Lockhart D.C** (2004) Drivers and barriers to seeking treatment for erectile dysfunction: a comparison of six countries. BJU Int 94: 1055–65

**Shadlen, K., Guennif, S. & Guzman, A** (2013) Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries. 1st ed. London: Edward Elgar Publishing Ltd

**Shajarizadeh, A., and Hollis, A.** (2015). Price-cap regulation, uncertainty and the price evolution of new pharmaceuticals. Heal. Econ. (United Kingdom) *24*, 966–977.

**Sharp, P.M., and Hahn, B.H.** (2011). Origins of HIV and the AIDS pandemic. Cold Spring Harb. Perspect. Med. *1*.

**Siddiqui, M., and Rajkumar, S.V.** (2012). The high cost of cancer drugs and what we can do about it. Mayo Clin. Proc. *87*, 935–943.

**Sims D.E, Salas E & Burke S.C** (2004) is there a “big five” in teamwork? Chicago, IL. 19th annual meeting of the Society for Industrial and Organizational Psychology

**Sirota, M., Dudley, J.T., Kim, J., Chiang, A.P., Morgan, A.A., Sweet-Cordero, A., Sage, J., and Butte, A.J.** (2011). Discovery and preclinical validation of drug indications using compendia of public gene expression data. Sci. Transl. Med. *3*, 96ra77.

**Smith, R. & Hanson, K** (2011) Health Systems in Low- and Middle-Income Countries: An economic and policy perspective. 1st ed. Oxford: OUP Oxford

**Solomon S** (2007) BC woman killed by fake drugs bought online: 'Metal toxicity' from counterfeit pills reinforces danger of Internet meds. National Review of MedicineAvailable:http://www.nationalreviewofmedicine.com/issue/2007/07_30/4_policy_politics_13.htmlLast Accessed: 03/08/14

**Song, C.H., and Han, J.-W.** (2016). Patent cliff and strategic switch: exploring strategic design possibilities in the pharmaceutical industry. Springerplus *5*, 692.

**Song, Y., Bian, Y., Petzold, M., Li, L., and Yin, A.** (2014). The impact of China¿s national essential medicine system on improving rational drug use in primary health care facilities: an empirical study in four provinces. BMC Health Serv. Res. *14*, 507.

**Soumerai S.B & Avorn J** (1990) Principles of educational outreach ("academic detailing") to improve clinical decision taking. Journal of the American Medical Association 263: 549-556

**Spilsbury, R** (2014) Global Industries Uncovered: The Pharmaceutical Industry. 1st ed. London: Wayland

**Sprent, P.** (2003). Statistics in medical research. Swiss Med. Wkly. *133*, 522–529.

**Sri Lanka Ministry of Health Care & Nutrition (SL-MHCN)** (2009) National List of Essential Medicines 4th Revision, Report of the Expert Committee on Essential Medicines

**Stacey, M** (1985): *Methods of Social Research*, Pergamon Press, Oxford.

**Stiftung, E.** (2012). The Health System in Namibia.

**Strang, J., Babor, T., Caulkins, J., Fischer, B., Foxcroft, D., and Humphreys, K.** (2012). Drug policy and the public good: Evidence for effective interventions. Lancet *379*, 71–83.

**Subramanian, A** (2004) Medicines, Patents and TRIPS-Finance and development has the intellectual property pact opened a Pandora's Box for the pharmaceutical industry?, [March2004]. Available form

http://www.imf.org/external/pubs/ft/fandd/2004/.../subrman.pdf

**SUKL** (2010) What is pharmacovigilance SUKL state institute for drug control Available: http://www.sukl.eu/medicines/what-is-pharmacovigilance Last Accessed: 03/08/14

**Sultanate of Oman Ministry of Health** (2004) The Directorate General of Pharmaceutical Affairs and Drug Control Aims, Present Situation and Future Policy Recommendations

**Tailal** (2008) Importance of Human Resource Development Studymode Available from:http://www.studymode.com/essays/Importance-Of-Human-Resource-Development-153820.html Last Accessed: 03/08/14

**Tanzi, R.E., and Bertram, L.** (2005). Twenty years of the Alzheimer's disease amyloid hypothesis: A genetic perspective. Cell *120*, 545–555.

**Tarloff, B** (2007) Adverse Drug Reactions. PhD, [last full review/revision August 2007].Available from:http://www.merckmanuals.com/home/drugs/adverse_drug_reactions/benefits_versus_risks_of_drugs.html

**Taylor E & Renner M.** (2003) Analyzing Qualitative Data: Development and Evaluation, University of Wisconsin-Extension. Available from

learningstore.uwex.edu/pdf/g3658-12.pdf - United States

**Taylor P** (2011) Council of EU adopts falsified medicines directive. Available from: http://www.securingpharma.com/40/articles/947.php Last accessed 03/08/14

**Tetteh,E.K.** (2009) Policies and institutional arrangements for rationalizing drug selection and consumption patterns in African healthcare systems. UK: Office of Health Economics

**Todd, J.A.** (2010). Etiology of type 1 diabetes. Immunity *32*, 457–467.

**Trace M** (2010) Drug Policy: Lessons Learnt and Options for the Future, Global Commission on Drug Policies

**Trap, B., Chinyanganya, F. & Hogerzeil, H** (2006) How to support a national essential drugs programme by repeated surveys of the pharmaceutical sector. 1th ed. Geneva: World Health Organisation

**Transform Drug Policy Foundation (TDPF)** (2009) After the War on Drugs: Blueprint for Regulation

**Triggle, D.J** (2007) Treating desires not diseases: a pill for every ill and an ill for every pill? *Drug Discovery Today* 12(3/4): 161-166

**Turner, B** (2012) U.S. National Drug Control Strategy (Drug Transit and Distribution, Interception and Control). 1th ed. London: Nova Science Publishers

**Uganda Ministry of Health** (2002) National Drug Policy 1st Edition, [October 2002]. Available from:

apps.who.int/medicinedocs/documents/s16463e/s16463e.pdf

**UNICEF** (2004) New agreements aim to make lowest-cost AIDS drugs and diagnostics Available to hundreds of thousands in developing world, [6 April 2004]. Available form

http://www.unicef.org/media/media_20329.htm

**United Nations** (1995) Recommended guidelines for quality assurance and good laboratory practices: Manual for use by national laboratories United Nations International Drug Control Programme Available from: https://www.unodc.org/documents/scientific/st-nar-25.pdf Last Accessed: 02/08/14

**U.S. Government Accountability Office (GAO)** (2011) Office of National Drug Control Policy: Agencies View the Budget Process as Useful for Identifying Priorities, but Challenges Exist, GAO-11-261R ONDCP's Budget Process

**Van Helden, P.D., van Helden, L.S., and Hoal, E.G.** (2013). One world, one health. EMBO Rep. *14*, 497–501.

**Warungo, J.** (2013). Is Kenya having a mid-life crisis?

**Watal, J** (2000). Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It? Science, Technology and Innovation Discussion Paper No. 8, Centre for International Development, Harvard University, and Cambridge, MA, USA

**Webb, M.B.** (1999). New Zealand's national drug policy. Drug Alcohol Rev. *18*, 435–440.

**Werb D, Rowell G, Guyatt G, Kerr T, Montaner J & Wood E** (2010) Effect of Drug Law Enforcement on Drug-Related Violence: Evidence from a Scientific Review International Centre for Science in Drug Policy: Canada

**White T.J, Arakelian A & Rho J.P** (1999) Counting the costs of drug-related adverse events. Pharmacoeconomic 15(5): 445-58

**Williams HA, et al** (2004) The process of changing national malaria treatment policy: lessons from country level studies, Health Policy Plan19:356-370

**Williams, L.J. and Abdi, H.,** 2010. Post-hoc comparisons. *Encyclopedia of Research Design*.

**Williams, M** (2001) The TRIPS and Public Health Debate : An Overview. International Gender and Trade Network . Available form:

http://www.commerce.nic.in/TRIPS_matter_amended.pdf

**Wilson, F. & Mabhala, A** (2008) Key Concepts in Public Health (SAGE Key Concepts series). 1th ed. London: SAGE Publications Ltd

**Wondemagegnehu, E. and World Health Organization,** 1999. Counterfeit and substandard drugs in Myanmar and Viet Nam: report of a study carried out in cooperation with the Governments of Myanmar and Viet Nam.

**Wonderling, D., Gruen, R. & Black, N** (2005) Introduction to Health Economics (Understanding Public Health). 1st ed. London: Open University Press

**Woods,M.** (2011) Interviewing for research and analysing qualitative data, [March 2011]. Available from

owll.massey.ac.nz/.../interviewing-for-research-and-analysing-qualitative-data

**World Health Organization** (1987) The rational use of drugs. Report of the conference of experts, Nairobi, 25-29 November 1985. World Health Organisation, Geneva, Switzerland.

**World Health Organization** (1992) Good manufacturing practices for pharmaceutical products, WHO Expert Committee on Specifications for Pharmaceutical Preparations, 32nd Report, WHO Technical Report Series No. 823, Annex 1

**World Health Organization** (1998) General guidelines for methodologies on research and evaluation of traditional medicine. 1th ed. Geneva: World Health Organisation

**World Health Organization** (1999) Indicators for monitoring national drug policies. 1th ed. Geneva: World Health Organisation

**World Health Organization** (1999) Operational principles for good pharmaceutical procurement. Geneva, World Health Organization, 1999 (WHO/EDM/PAR/99.5)

**World Health Organization** (1999) Progress in Essential Drugs and Medicines Policy 1998-1999. Available from:

http://www.apps.who.int/medicinedocs/en/d/Jh2950e/2.2.html

**World Health Organization** (2000) Global comparative pharmaceutical expenditures with related reference information. *Health Economics and Drugs* EDM series no. 3 (EDM/PAR/2000.2) p56

**World Health Organization** (2000) WHO Medicines Strategy: Framework for action in Essential Drugs and Medicines Policy 2000-2003. Available from:

http://www.apps.who.int/medicinedocs/fr/d/Jwhozip16e/8.1.html

**World Health Organization** (2000) Safety Monitoring of Medicinal Products: Guidelines for Setting up and a Pharmacovigilance Centre. WHO: Essential Medicines and health Products Information Portal. Available:

http://apps.who.int/medicinedocs/en/d/Jh2934e/4.1.html Last Accessed: 03/08/14

**World Health Organization** (2000) the use of essential drugs. Ninth report of the WHO Expert Committee (including the revised Model List of Essential Drugs). Geneva, World Health Organization, 2000 (WHO Technical Report Series,

**World Health Organization** (2001) How to develop and implement a national drug policy, 2nd Edition - Updates and replaces, *Guidelines for Developing National Drug Policies, 1988*

**World Health Organization** (2001) How to Develop and Implement a National Drug Policy (second edition), [7 Feb 2011]. Available from:

http://www.who.int/medicinedocs/end/Js2283e/

**World Health Organization** (2001) Impotence of Legislations and Regulations. How to Develop and Implement a National Drug Policy 2nd Edition pp-1-96

**World Health Organization** (2001) Key Components of a National Drug Policy. How to Develop and Implement a National Drug Policy 2nd Edition pp-1-96

**World Health Organization** (2001) Overview of the National Drug Policy Process. How to Develop and Implement a National Drug Policy 2nd Edition pp-1-96

**World Health Organization** (2001) What is a National Drug Policy. How to Develop and Implement a National Drug Policy 2nd Edition pp-1-96

**World Health Organization** (2001) Framework for Drug Legislation. How to Develop and Implement a National Drug Policy 2nd Edition pp-1-96

**World Health Organization** (2002) Effective drug regulation: A multicountry study, 1th ed. London: World Health Organisation

**World Health Organization** (2002) Essential Drugs and Medicines Policy: Supporting countries to close the access gap, WHO Annual report

**World Health Organization** (2002) Promoting Rational Use of Medicines: Core components, WHO annual report

**World Health Organization** (2002) The Importance of Pharmacovigilance- Safety Monitoring of Medicinal Products. WHO Essential Medicines and Health Products Information Portal pp. 1- 52

**World Health Organization** (2002) The Selection of Essential Medicines, Policy Perspectives on Medicines: WHO annual report

**World Health Organization** (2003) Drug and Therapeutic Committees – A Practical Guide Available: http://apps.who.int/medicinedocs/en/d/Js4882e/3.1.html Last Accessed: 02/08/201

**World Health Organization** (2003) Guide to good storage practices for pharmaceuticals. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-seventh report. Geneva, (WHO Technical Report Series, No. 908). Annex 9

**World Health Organization** (2003) How to Develop and Implement a National Drug Policy, WHO Policy Perspectives on Medicines

**World Health Organization** (2003) How to Develop and Implement a National Drug Policy, [January 2003]. Available from:

http://www.who.int/managment/background_4b.Pdf

**World Health Organization** (2003) Introduction to drug utilization research, Geneva: World Health Organization, [cited 2008 Feb 25]. Available from: http://www.merckmanuals.com/home/drugs/administration_and_kinetics_of_drugs/drug_distribution.html

**World Health Organization** (2003) Medicines Strategy Framework for Action in Essential Drugs and Medicines Policy 2000-2003. Available from: http://www.apps.who.int/medicinedocs/en/d/Jwhozip16e/8.html Last Accessed: 03/08/14

**World Health Organization** (2003) Procedure for Assessing the Acceptability, in Principle, of pharmaceutical products for Purchase by United Nations agencies. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-seventh report. Geneva, (WHO Technical Report Series, No. 908), Annex 8. Available from http://www.who.int/medicines/qsm/trs908/trs908.pdf

**World Health Organization** (2003) *The* Selection and Use of Essential Medicines - WHO Technical Report Series, No. 914 Available from: http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html Last Accessed: 02/08/2014

**World Health Organization** (2003) WHO Medicines Strategy. Framework for action in essential drugs and medicines policy. 1th ed. Geneva: World Health Organisations

**World Health Organization** (2004) Establishing or maintaining domestic production of pharmaceuticals in developing countries. 1th ed. Geneva: World Health Organisation

**World Health Organization** (2004) Equitable Access to Essential Medicines: A framework for collective Action-who policy perspective on medicines, No.008, [March2004] Available form

http://www.who.int/medicinedocs/en/d/Js4962e/

**World Health Organization** (2004) THE Doha Declaration on the TRIPS Agreement and Public Health. Available form

http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html

**World Health Organization** (2004) World Medicine Situation. Geneva: WHO

**World Health Organization** (2005) How to develop and implement a national drug policy, Geneva: World Health Organisation

**World Health Organization** (2006) Counterfeit medicines: an update on estimates Available from: http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf Last Accessed: 03/08/2014

**World Health Organization** (2006) Multisource (generic) Pharmaceutical Products: guidelines on registration requirements to establish interchange ability. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth report. Geneva: WHO; 2006 [cited 2008 Jan 19]. p. 347-390. (WHO Technical report series; no 937, annex 7).

**World Health Organization** (2007) A Model Quality Assurance System for Procurement Agencies: Recommendations for Quality Assurance Systems Focusing on Prequalification of Products and Manufacturers, Purchasing, Storage and Distribution of Pharmaceutical Products. Available from: http://www.who.int/medicines/publications/ModelQualityAssurance.pdf Last Accessed: 02/08/14

**World Health Organization** (2007) A Model Quality Assurance System for Procurement Agencies: Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage, and distribution of pharmaceutical products. Previously published as Annex 6 of the 40th Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No. 937, Geneva, World Health Organization, 2006)Available from: http://www.myaccessrh.org/documents/10157/37547/ModelQualityAssurance.pdf Last Accessed: 03/08/14

**World Health Organization** (2007) International non-proprietary names (INN) for Pharmaceutical Substances [CD-ROM]. Geneva: World Health Organization; 2007. Available from: URL:http://bookorders.who.int/bookorders/anglais/ qsearch1.jsp?sesslan=1

**World Health Organization** (2007) The Selection and Use of Essential Medicines. Technical report series No 946. Geneva: WHO

**World Health Organization** (2007) WHO Technical Report Series 950 - The Selection and Use of Essential Medicines - Report of the WHO Expert Committee (including the Model List of Essential Medicines for Children)

**World Health Organization** (2010) Medicines: spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines, Available from: http://www.ideaconnection.com/solutions/534-Counterfeit-drugs.html

**World Health Organization** (2010) WHO model formulary for children - Based on the second model list of essential medicines for children 2009

**World Health Organization** (2011) Rational use of medicines. Available online at: http://www.who.int/medicines/areas/rational_use/en/ accessed on 17th May 2011

**World Health Organization** (2011) Sixth- Fourth World Health Assembly, substandard/spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products, Report by director general, 2011

**World Health Organization** (2013) External Quality Assurance Assessment Scheme: Medicines Available from: http://www.who.int/medicines/areas/quality_safety/quality_assurance/qas_eqaas/en/ Last Accessed: 03/08/14

**World Health Organization** (2013) Prequalification of medicines. Fact Sheet Number 278 Available: http://www.who.int/mediacentre/factsheets/fs278/en/ Last Accessed 03/08/14

**World Health Organization** (2014) Content Sheet 10-1: Overview of External Quality Assessment (EQA) Available form: http://www.who.int/ihr/training/laboratory_quality/10_b_eqa_contents.pdf?ua=1 Last Accessed: 03/08/14

**World Health Organization** (2014) Essential Medicines Available from: http://www.who.int/medicines/services/essmedicines_def/en/ Last Accessed: 02/08/14

**World Health Organization** (2014) Quality Assurance: In vitro diagnostics and laboratory technology Available form: http://www.who.int/diagnostics_laboratory/quality/en/ last accessed: 03/08/14

**World Health Organization** (2015) Essential Medicines and Health Products Information Portal. [Online] Available at: http://apps.who.int/medicinedocs/en/d/Js2283e/ [Accessed 23 August 2015].

**World Health Organization** (2015) News and top stories. [Online] Available at: http://www.who.int/en/ [Accessed 23 August 2015]

**World Health Organization** (2015). Ghana Tuberculosis Profile.

**Wong B.M, Etchells E.E & Kuper A** (2010) Teaching quality improvement and patient safety to trainees: a systematic review. Acad Med; 85(9):1425-39

**Xie, H.-G., and Frueh, F.W.** (2005). Pharmacogenomics steps toward personalized medicine. Per. Med. *2*, 325–337.

**Yusuff, K.B., and Tayo, F.** (2004). Drug supply strategies, constraints and prospects in Nigeria. Afr J Med Med Sci *33*, 389–394.

**Zadeh, A.N. (2013)**. Pharmaceutical economics. Life Sci. J. *10*, 226–229.

**Zibran, M.F.** (2015). Chi-squared test of independence. Handb. Biol. Stat. 1–7.

# Appendices

**Appendix I:** The Information Background to the Interviews with Health Professionals.

**Appendix II:** A letter from The Assistant Undersecretary of Drugs and Medical Supply Affaires in the Kuwaiti Ministry of Health (Dr. Omar AL Sayed) to the Secretary – General of Kuwait Institution for Medical Specialties to support and facilitate the work of the author in the collection of the necessary data from Kuwaiti Ministry of Health for this PhD study.

**Appendix 1:**

## Interview

### Establishing of National Drug Policy
### In the State of Kuwait

The National drug policy is official documents for the pharmaceutical sector which plays as a guide for action and commitment to a goal.
It provides a common frame work for both activities either public sector or private sector to achieve the health for all.

The aims of policy:
To use safe and effective drugs and ensure drug quality and availability.

The majors objectives of National Drug Policy are:

1. Access to the drug and affordability through appropriate selection.
2. Improve drug management.
3. Ensure quality, safety and efficacy of drugs.
4. Ensure rational use of drugs.

The Aim of this dissertation is to establish a national drug policy for the pharmaceutical sector in the State of Kuwait, by designing guidelines that regulate, develop and monitor the health care system.
Interview will take part with all health professional groups in the State of Kuwait to take their advices, opinions and recommendations which help to fulfill the aim of this dissertation.
Taking part in this interview is completely optional. All information will be kept confidential and will be used for the purpose of the research only.

Thank you for your participation.

1

Name of interviewer:.....

Job Title:.....

Date (dd/mm/yy):.....

Signature:.....

1. How important is having a National Drug Policy?

**1. Very important** ☐ **2.Important** ☐ **3.Not applicable** ☐
**4. Not important** ☐ **5.Usless** ☐

**Please explain**.....
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2. Do you think we can develop and improve the health care system in Kuwait?

**1. Yes** ☐ **2. No** ☐

**How**.....
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3. Are there any issues of concern with the organization of the health care system in State of Kuwait?

**1. Strongly agree** ☐ **2. Agree** ☐ **3. Not applicable** ☐
**4. Disagree** ☐ **5. Strongly disagree** ☐

**Please explain**.....
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4. In public and private sector, do you think we have enough control over regulating the process associated with pharmaceuticals?

**1. Yes** ☐ **2. No** ☐

**If No, Please explain**.....
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5. Do you feel that the training of health professionals in public and private sectors is sufficient?

**1. Yes** ☐ **2. No** ☐

**Please explain**.....
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6. Do you think that the price range of medication in the private sector is publically acceptable?

**1. Strongly agree** ☐ **2. Agree** ☐ **3. Not applicable** ☐
**4. Disagree** ☐ **5. Strongly disagree** ☐

**Please explain**.....
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7. Do you think that there are any issues with the access to quality, safety and efficacy drugs?

**1. Yes ☐** **2. No ☐**

**How?**.....
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8. Do you think that there is irrational use of drugs in Kuwait?

**1. Strongly agree ☐** **2. Agree ☐** **3. Not applicable ☐**
**4. Disagree ☐** **5. Strongly disagree ☐**

**How?**.....
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9. How important is having an essential drug list?

**1. Very important☐** **2.Important ☐** **3.Not applicable ☐**
**4. Not important ☐** **5.Usless ☐**

**How?**.....
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10. Do you think that the State of Kuwait should develop its own pharmaceutical industries?

**1. Yes** ☐ **2. No** ☐

**Explain how can we develop?**.....
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11. Do you think its time to establish a National Drug Policy in Kuwait?

**1. Yes** ☐ **2. No** ☐

**Please explain**.....
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12. If yes.
Do you think it will influence the health care system in Kuwait?

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**Appendix 2:**

AL-CANADY
Translation Co.

الكندي

شركة
الكندي
للترجمة

Medicines and Medical Supplies

Reference: WME/554

Date: 4/4/2012

Secretary-General of Kuwait Institution for Medical Specialties

Dear Sir,

**Sub. Facilitation of Pharmacist task/ Khalid Yousef Ahamd Al Ali**

Kindly be informed that the above mentioned is working at Admin of Medicine Registration and Control of Botanical and Medical Medicines to get doctorate degree as the above mentioned has submitted to request necessary information to doctorate research in pharmaceutical services and medicine control in the following Admin:

1- Admin of Medicine Registration and Control of Botanical and Medical Medicines.
2- Admin of Medicines Inspection.
3- Admin of Medical Storages.
4- Admin of Pharmaceutical Services.
5- Faculty of Pharmacy – Kuwait University.

Therefore, kindly approve facilitation of the mission for the above mentioned as per applicable regulation.

Best regards

Assistant Undersecretary

For Medicines and Medical Supplies Affairs

Original received

Date: 5/4/2012

هذه ترجمة صحيحة للنص المرفق
بتاريخ ...
Certified True and Correct Translation
of The Attached Text

الكويت - حولي شارع ابن خلدون الرئيسي - مجمع الغريب - بجانب بنك بيت الكويت الكويتي تلفون: ٢٢٦٤٤٣٥٠ - ٢٢٦٤٤٣٥٥ (٠٠٩٦٥)
Kuwait - Hawalli - Ibn Khaldoon St. - Al Ghareeb Commercial Complex - Beside KFH Branch Tel.: (+965) 22644350 - 22644355
E-mail: al-canady_translation@hotmail.com

Medicines and Medical Supplies

Reference : .....

Date :

الأدوية والتجهيزات الطبية

الرقم : .....

التاريخ : ٤ / ٤ / ٢٠١٤ م

السيد الفاضل / أمين عام معهد الكويت للإختصاصات الطبية المحترم

تحية طيبة وبعد ،،،

الموضوع : تسهيل مهمة الصيدلي / خالد يوسف أحمد العلي

نحيطكم علماً بأن المذكور أعلاه يعمل بإدارة تسجيل ومراقبة الأدوية الطبية والنباتية وهو بصدد التحضير لرسالة الدكتوراه، وحيث أن المذكور تقدم بطلب المعلومات اللازمة لبحث الدكتوراه في مراقبة الأدوية والخدمات الصيدلانية في كل من الإدارات التالية :

١- إدارة تسجيل ومراقبة الأدوية الطبية والنباتية.

٢- إدارة تفتيش الأدوية.

٣-إدارة المستودعات الطبية.

٤- إدارة الخدمات الصيدلانية.

٥- كلية الصيدلة – جامعة الكويت.

٦- مركز دسمان للسكر.

لذا يرجى التكرم بعد الموافقة نحو تسهيل مهمة المذكور أعلاه حسب النظام المتبع لديكم.

وتفضلوا بقبول فائق الإحترام ،،،

وكيل الوزارة المساعد

لشئون الأدوية والتجهيزات الطبية

د/ [illegible]

وكيل الوزارة المساعد لشئون الأدوية والتجهيزات الطبية

إستلمت الأصل

الإسم والتوقيع : [illegible]

التاريخ : ٥ / ٤ / ٢٠١٤